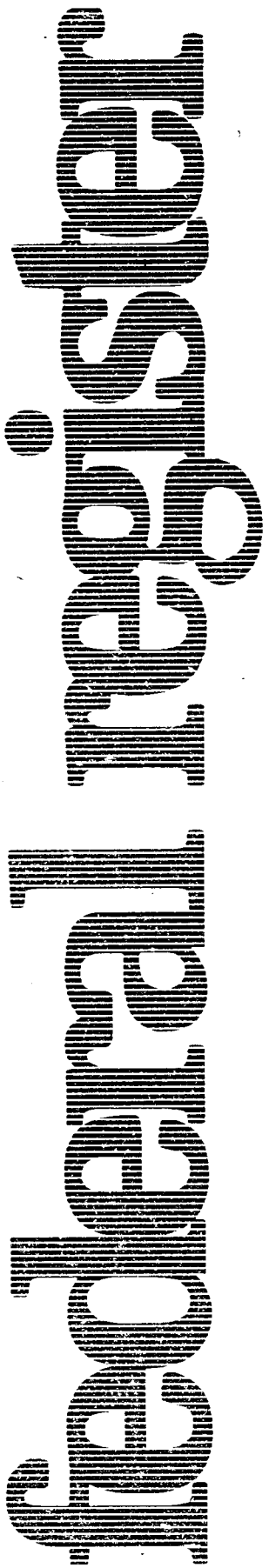

Friday
May 13, 1983

Part II

Environmental Protection Agency

Premanufacture Notification; Premanufacture Notice Requirements and Review Procedures; Final Rule and Notice Form

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 720

[OPTS-50002G; TSH-FRL 2998-5]

Premanufacture Notification; Premanufacture Notice Requirements and Review Procedures

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule and notice form.

SUMMARY: This rule establishes premanufacture notice requirements and review procedures under section 5 of the Toxic Substances Control Act ("TSCA" or "the Act"). Section 5 of TSCA requires persons to notify EPA at least 90 days before manufacturing or importing a new chemical substance for commercial purposes. On January 10, 1979, EPA proposed a rule and forms to implement the section 5 notice requirements; the rule and forms were reproposed in part on October 16, 1979, and supplemented by a processor reporting proposal on August 15, 1980 and a clarification of importer reporting requirements on September 23, 1980. In this notice, EPA is issuing a final rule and notice form. The notice requirements and procedures established in this rule will replace the Interim Policy under which EPA has been conducting the new chemical notice review program since it began on July 1, 1979.

DATE: This rule is effective July 12, 1983.

FOR FURTHER INFORMATION CONTACT: Jack P. McCarthy, Director, Industry Assistance Office (TS-799), Office of Toxic Substances, Environmental Protection Agency, Rm. E-511, 401 M St., SW., Washington, D.C. 20460, Toll-free: (800-424-9065), in Washington, D.C.: (554-1404), Outside the USA: (Operator-202-554-1404).

SUPPLEMENTARY INFORMATION:

OMB Control Number 2070-0012.

This preamble discusses EPA's approach to implementing TSCA section 5 notice requirements, the provisions of this rule, and the contents of the notice form. EPA has also prepared several documents in support of this rule, including a Regulatory Impact Analysis, EPA's Response to Comments on Premanufacture Notice Requirements and Review Procedures for New Chemical Substances, and an Instructions Manual for Premanufacture Notification of New Chemical Substances ("Instructions Manual"). These documents are available from the Industry Assistance Office, Office of Toxic Substances (OTS), at the address above.

Following is an index to the remainder of this preamble.

I. Introduction

A. Statutory Framework

Under section 5(a) of TSCA, 15 U.S.C. section 2604(a), persons must notify EPA at least 90 days before manufacturing or importing a new chemical substance for commercial purposes. A new chemical substance, as defined in section 3(2) of the Act, is any chemical substance that is not included on the list, or "Inventory," of existing chemical substances, compiled by EPA under TSCA section 8(b). EPA first published the TSCA Chemical Substance Inventory on June 1, 1979, and amended it in July 1980 and May 1982, with Cumulative Supplements. The Inventory is also regularly updated by the addition of new chemical substances which have undergone section 5 review and have entered commercial production.

Section 5(d)(1) of the Act specifies information that submitters must provide in section 5(a) notices: (1) test data in their possession or control; (2) descriptions of health and environmental effects data that they know or can reasonably ascertain; and (3) known or reasonably ascertainable information on chemical identity; proposed categories of use; proposed volume of production; byproducts resulting from manufacture, processing, use, or disposal; workplace exposure; and manner or method of disposal. Section 5(b) of the Act imposes additional data requirements for chemical substances subject to testing rules under section 4 and for chemicals that EPA, by rule under section 5(b)(4), has determined may present unreasonable risks of injury to health or the environment.

Once EPA receives a section 5 notice, EPA has 90 days to review it, unless for good cause EPA extends the review period under section 5(c) for up to an additional 90 days. During the review period, EPA may act under section 5(e) or 5(f) to regulate the production or use of the new chemical substance. Section 5(e) authorizes EPA to prohibit or limit the manufacture (including import), processing, distribution in commerce, use, or disposal of a new chemical

substance until information sufficient to evaluate its health and environmental effects is provided. EPA can take this action if it determines that the available information is insufficient for a reasoned evaluation and either (1) the substance may present an unreasonable risk of injury to health or the environment, or (2) the substance will be produced in substantial quantities and there may be significant or substantial human exposure to the substance or substantial release to the environment. Under section 5(f), EPA may regulate a new chemical substance if it finds that there is a reasonable basis to conclude that the manufacture, processing, distribution in commerce, use, or disposal of the substance will present an unreasonable risk of injury to health or the environment.

If EPA has not prohibited manufacture or import of the chemical substance during the review period, these activities may begin as soon as the review period expires, subject to restrictions or testing requirements imposed during the review period. When manufacture or import begins and the notice submitter provides a notice of commencement, EPA adds the substance to the inventory. Thereafter, any person may manufacture or import the substance without submitting a section 5 notice to EPA (unless EPA has issued a significant new use rule on the chemical under section 5(a)(2)).

Certain chemicals are exempt from the section 5 notice requirements. They include categories of substances excluded from the TSCA definition of chemical substance: tobacco and tobacco products; nuclear materials; firearms and ammunition; and substances used solely as pesticides, foods, food additives, drugs, or cosmetics. In addition, section 5(h) authorizes exemptions from section 5 notice requirements for new chemical substances produced for test marketing or research and development, and for substances which exist temporarily as a result of a chemical reaction in the manufacture or processing of another chemical substance to which there is no human or environmental exposure. Also, under section 5(h)(4) EPA may, upon application and by rule, exempt the manufacturer or importer of any new chemical substance from all or part of the section 5 requirements if the Agency determines that the manufacture, processing, distribution in commerce, use, and disposal of the substance will not present an unreasonable risk of injury to health or the environment.

Section 5(d)(2) of the Act requires EPA to publish certain information on section 5 notices in the **Federal Register**, including at the least: (1) information on the identity and uses of the new substance, (2) a description of test data submitted under section 5(b), and (3) the results of the tests. In addition, at the beginning of every month, EPA must publish a list of: (1) new chemical substances undergoing section 5 review and (2) new chemical substances for which the notice review periods have expired since the previous monthly **Federal Register** notice.

Under section 14 of the Act, EPA is prohibited from disclosing confidential business information submitted under TSCA, including section 5, except in certain circumstances. Specifically, EPA may disclose confidential business information if it determines that disclosure is necessary to protect human health or the environment against an unreasonable risk of injury to health or the environment, and, to the extent necessary, if the information is relevant in any proceeding under the Act. Also, EPA is not prohibited from disclosing health and safety studies (including underlying data) on chemical substances for which a section 5 notice was received. However, the Act does not authorize EPA to reveal any such data that would disclose confidential processes or portions of a mixture.

B. Background

Section 5 notice requirements went into effect on July 1, 1979, 30 days after the publication of the Initial Inventory. On that date, persons who intended to manufacture new chemical substances, or import them in bulk, became subject to section 5 notice requirements. On July 30, 1980, EPA published a Cumulative Supplement to the Initial Inventory, which included chemical substances reported by processors and users and substances imported as part of mixtures or articles. This supplement, together with the Initial Inventory, make up the Revised Inventory. Thirty days after publication of the Revised Inventory, on August 30, 1980, section 5 notice requirements went into effect for persons who imported new chemical substances as part of a mixture. Under the Interim Policy and this final section 5 notice rule, importers of new chemical substances as part of an article are not subject to the section 5 notification requirements.

Since section 5 notice requirements went into effect, EPA has operated the notice review program under an Interim Policy. In the preamble to the January 10, 1979, proposed section 5 notice rule, EPA announced its Interim Policy for handling notices submitted before the publication of the Inventory. EPA modified this policy in an Interim Policy Statement published in the **Federal Register** of May 15, 1979 (44 FR 28564). This statement extended the Interim Policy's coverage to all notices filed before the effective date of the final section 5 rule and notice form.

EPA issued a Revised Interim Policy Statement in the **Federal Register** of November 7, 1980 (45 FR 74378). This statement clarified the May 15 statement and discussed in more detail the type of information EPA expected to receive in notices, EPA's interim procedures for handling confidential information, and procedures for submitting and reviewing test-marketing exemption applications. The operation of the review program under the Interim Policy is discussed later in this preamble.

EPA proposed a rule to implement section 5 notice requirements in the **Federal Register** of January 10, 1979 (44 FR 2242). This proposal included a description of the applicability of section 5 requirements, the general procedures for submitting notices, information requirements in the notices, and EPA's procedures for processing information in notices, including confidential business information. EPA also proposed notice forms for manufacturers, importers, foreign manufacturers and suppliers, and processors and customers.

In response to public comment on the January 10 proposal, EPA reproposed certain parts of the rule and forms in the **Federal Register** of October 16, 1979 (44 FR 59764). In particular, the reproposal shortened the notice form, reducing the information required; it revised procedures for asserting and substantiating claims of confidentiality; and it revised the proposed supplemental reporting requirement under section 8(a) of TSCA. In addition, EPA proposed in the **Federal Register** of August 15, 1980 (45 FR 54642) that persons notify EPA before they processed for TSCA commercial purposes substances that were manufactured or imported for purposes exempt from TSCA reporting. In the **Federal Register** of September 23, 1980, EPA proposed a clarification of reporting responsibilities of importers in the January proposal (45 FR 63806). Finally, EPA issued a statement in the **Federal Register** of July 2, 1982 (47 FR 28969) stating that, under the Interim Policy, submitters were no longer required to substantiate confidentiality claims at the time a notice is submitted.

With this notice, EPA is now promulgating final section 5 notice requirements and review procedures. This rule modifies the earlier proposals

in light of EPA's experience under the Interim Policy and public comments on the rule. The rule will become effective 30 days after publication of this notice. Until then, EPA will continue to operate the notice review program under the Interim and Revised Interim Policy Statements.

II. General Approach to Notice Review

In conducting its review of a new chemical substance, EPA assesses the risks associated with all phases of the life cycle of the substance, including its manufacture, import, processing, distribution in commerce, use, and disposal. The review is based on information provided by the submitter in the notice and on information EPA may obtain elsewhere, for example, in the literature searches on new substances and their structural analogues that EPA conducts as part of its new chemical review. However, it is ultimately the notice submitter's responsibility to provide enough information for an adequate risk assessment.

In conducting its review, EPA considers a number of different factors, including the potential toxicity of the substance which is determined from test data submitted in the notice or obtained elsewhere, data on structural analogues, and structure-activity analyses. EPA also reviews the potential for humans and the environment to be exposed to the substance during uses proposed by the notice submitter. Also, because EPA must assess the "reasonableness" of any risk, it considers such nonrisk factors as the possible economic benefits of the substance and the availability of substitutes—or whether a substance is intended as a substitute for a more toxic substance.

Because the Act explicitly requires EPA to assess risks associated with the entire life cycle of new chemicals, EPA evaluates both the new chemical substance and related substances, such as impurities, byproducts, degradation products, unintended reaction products, and other chemical substances associated with the manufacture, processing, distribution in commerce, use, or disposal of the new chemical substance, even if these related substances are on the Inventory.

On the basis of its assessment, EPA may take action during the review period under section 5(e) to regulate the substance while EPA obtains more data, or under section 5(f) to regulate manufacturing, processing, distribution in commerce, use, or disposal, if EPA determines that the substance will present an unreasonable risk. EPA may also issue a follow-up reporting requirement under section 5(a)(2) or 8(a) or regulate the chemical under section 5(b)(4) (risk list). EPA, however, can regulate a substance only if it takes positive action, either by order or by rule. Without such action during the review period, a substance can enter commercial production unregulated under TSCA. As a result, section 5 of the Act does not establish a registration program, and EPA has not in any sense "approved" substances that have passed through review without regulation.

From commencement of the notice review program on July 1, 1979, to March 31, 1983, EPA received 2,201 valid premanufacture notices. Of the total number, the review period had expired on 1,878 and 777 had entered commercial production. In addition, EPA reviewed 196 test-marketing exemption applications under section 5(h)(1) of the Act and granted 173 such exemptions. During this period, EPA issued seven section 5(e) orders regulating the production of 18 new chemical substances pending the development of additional data, and entered into voluntary control agreements with the submitters of 49 notices. In addition, submitters withdrew nine section 5 notices in the face of likely regulation.

Under the Interim Policy, EPA has gained experience in reviewing notices, which it has used in developing the final section 5 notice rule, and it has established review procedures that will continue when this rule is effective. The following sections outline our general review procedures for notices on new chemicals.

A. Notice Review Process

The notice review process established by EPA has six major phases: prenotice communication, process start-up, initial review, detailed review, regulatory response, and process closeout. All new chemicals are not subject to each phase.

1. *Prenotice Communication.* The EPA Office of Toxic Substances, which is responsible for the section 5 notice review program, employs a Prenotice Communications Coordinator to assist persons preparing a notice or considering the submission of a notice. The Prenotice Communications Coordinator provides guidance on a wide variety of topics, and refers persons to the appropriate EPA staff members for guidance on other questions. Topics for prenotice inquiries include the scope of TSCA and this rule, the contents of the TSCA Chemical Substance Inventory, the notice form, section 5 exemptions, premanufacture testing, confidentiality and generic name development, and notice review procedures.

The Prenotice Communications Coordinator can be reached by telephone at 202-382-3745 or by writing to the Prenotice Communications Coordinator, Chemical Control Division (TS-794), Environmental Protection Agency, 401 M Street, SW., Washington, D.C. 20460.

2. *Process Start-up.* Process start-up begins when EPA receives a notice. The OTS Document Control Officer assigns a premanufacture notice number to the notice and acknowledges the receipt of the notice to the submitter. The acknowledgment includes the date when the OTS Document Control Office received the notice. The 90-day review period begins on the date of receipt.

During process start-up, OTS staff review the notice to determine whether the substance and proposed uses are subject to section 5 notice requirements and whether all required information has been submitted. In addition, the Chemical Substance Inventory is searched to ensure that a section 5 notice is required, and the **Federal Register** notice required under section 5(d)(2) is prepared. This notice includes the identity of the new chemical substance; the premanufacture notice number; the name of the submitter; information on production, exposure, and use; and test results. Information claimed as confidential is omitted from the notice or masked by generic descriptions. At the same time, the OTS Reading Room establishes a public file containing a nonconfidential version of the notice.

A Notice Manager is assigned to each notice. The Notice Manager coordinates the review and serves as the EPA contact on all matters concerning the notice. Persons wishing to contact the managers of particular notices can obtain their names and telephone numbers from the Prenotice Communications Coordinator.

3. *Initial Review.* During the initial review period, EPA identifies chemical substances which require more detailed review and which are candidates for possible regulatory action. During this phase, EPA conducts a preliminary analysis of the chemical identity, physical and chemical properties, proposed uses, potential toxicity, environmental effects, human exposure, environmental release, and economic benefits. EPA uses the information contained in the notice, in certain cases searches the scientific literature for data on the substance and related substances, and, when necessary, seeks additional information from the submitter. Initial review ends when the staff reviews available risk data and

nonrisk information and decides whether more detailed review is necessary, possibly in support of an action under section 5(e) or 5(f), or under other sections of the Act.

4. *Detailed Review.* During detailed review, the Agency assesses the concerns it identified during initial review. EPA also examines the benefits to society of the new chemical substance and the availability of substitutes. After assessing the risks and certain nonrisk information, EPA analyzes possible regulatory or other control measures. If necessary, EPA extends the notice review period under section 5(c).

5. *Regulatory Response.* After completion of its detailed review, EPA may decide to regulate the substance during the review period. It may issue an order under section 5(e) if EPA finds that the substance may present an unreasonable risk of injury to health or the environment, or that it may be produced in substantial quantities, pending the development of additional data. EPA may control the substance under section 5(f) if it finds that the substance will present an unreasonable risk. EPA may also identify the substance as a candidate for regulation under section 5(a)(2), 5(b)(4), or 8.

6. *Process Closeout and Entry on the Inventory.* If EPA does not take action to regulate a substance during the review period, the submitter may manufacture or import the new chemical substance without restriction, as soon as the notice review period expires. The submitter must notify EPA by letter when manufacture or import begins. This letter must be sent to the Document Control Officer (TS–793), Office of Pesticides and Toxic Substances, 401 M Street, SW., Washington, D.C. 20460. This notice of commencement must contain: the specific identity of the chemical substance, its premanufacture notice number, and the date when manufacture or import begins. When EPA receives this letter, the substance is added to the Inventory.

B. Test-Marketing Exemption Applications

Under section 5(h)(1) of the Act, persons may apply for an exemption from section 5(a) or 5(b) reporting requirements to manufacture or import a new chemical substance for test-marketing purposes. EPA may grant an exemption if the applicant shows to EPA's satisfaction that the test-marketing activities will not present any unreasonable risk of injury to health or the environment. Therefore, EPA must make an affirmative finding that the test marketing will not present any unreasonable risk, and manufacture or import cannot begin until EPA grants the exemption. This standard differs from the finding EPA must make to take regulatory action on a new chemical under section 5(e); to act under section 5(e), EPA must conclude only that there may be an unreasonable risk. Under section 5(h)(6), EPA has only 45 days to approve or deny an exemption application. This limits the extent to which EPA can gather information beyond that contained in the test-marketing application.

To ensure an adequate review, test-marketing exemption applicants should include in their applications, at a minimum: (1) all existing data regarding health and environmental effects of the substance, including physical/chemical properties or, in the absence of such data, a discussion of toxicity based on structure-activity relationships and relevant data on chemical analogues; (2) the maximum amount to be manufactured or imported for test marketing; (3) the maximum number of persons who may be provided the substance during test maketing; (4) the maximum number of persons who may be exposed to the substance as a result of test marketing; (5) information on estimated duration and routes of exposure; and (6) a description of the test-marketing activity, including the length of time that will be required and how the activity may be distinguished from full-scale commercial production and from research and development. These items are set out in § 720.38(b) of the final rule.

C. Regulatory Actions

By March 31, 1983, EPA had issued seven orders under section 5(e) to control a total of 18 new chemical substances. The first three orders would have prohibited production of the new substances pending the development of further information. However, in each of the three cases, the manufacturer or importer withdrew its notice from review, rather than allow the order to go into effect. EPA also issued four consent 5(e) orders. These consent orders allow manufacture of the new chemical substance under specific restrictions pending the development of additional information. In addition, nine section 5 notices have been withdrawn by submitters in the face of likely regulation under section 5(e) or 5(f), but before orders were actually issued.

EPA has also reached voluntary agreements with a number of notice submitters rather than taking formal regulatory action. By March 31, 1983, the submitters of 19 notices had agreed to conduct testing in response to EPA concerns. Measures to control exposure, including labeling, Material Safety Data Sheets, and worker protection devices, where agreed to by the submitters of 30 notices, and the review periods for an additional 43 notices were suspended in response to EPA's concerns, to allow the submitters time to develop additional information voluntarily.

III. Provisions of the Rule

This unit discusses the provisions of the rule and specifically points out where these provisions differ from the January 1979, October 1979, and August 1980 proposals. In a separate document, Response to Comments on the Premanufacture Notice Requirements and Review Procedures, EPA discusses in more detail its response to comments on the earlier proposals. The Response to Comments is available in the OTS Public Reading Room.

A. Applicability

1. *Who Must Report.* Section 720.22 of the rule specifies who is subject to the section 5 notice requirements. These provisions closely follow those proposed in January 1979, which were based on the reporting requirements for the Initial Inventory. A detailed discussion of who must report follows.

a. *U.S. manufacturers.* Persons who intend to produce or manufacture a new chemical substance in the United States for a commercial purpose must submit a notice. Only manufacturers that are incorporated, licensed, or doing business in the United States may submit a notice. Persons who extract a new chemical substance from a previously existing substance, or a complex combination of substances, are manufacturers of that new chemical substance.

EPA has revised the definition of "manufacturer" in the final rule to include certain persons who contract with a manufacturer to make a chemical substance (sometimes known as "toll manufacture"). Under the definition in the final rule, a person who contracts with a manufacturer is also a manufacturer if the substance is manufactured or produced exclusively for that person, and that person specifies the identity of the substance and controls the total amount produced and the basic technology for the plant process. In this situation, the person who contracts with the actual manufacturer must submit the notice. This provision does not apply to the person who simply orders a specific chemical or a chemical with certain properties from a manufacturer. Instead, this provision only applies to the

situation where the person not only specifies the chemical identity, but spells out the basic process for making the chemical (althought the actual manufacturer may make adjustments in the specified process that are necessary to adapt the process to the manufacturer's own equipment.)

The rule further restricts this provision to persons who have an exclusive relationship with the manufacturer (i.e., the manufacturer does not sell the chemical to anyone else). As a result, the person placing the order also determines the total amount to be manufactured. Therefore, if more than one person orders the new chemical, neither of them has specified the total amount to be manufactured and neither is responsible for submitting the notice; instead, the person who actually manufactures the chemical must submit the notice.

EPA has added this provision to deal with the situation in which one person decides to manufacture a specified amount of a certain chemical using a certain process, but contracts with a manufacturer to actually make the chemical. In this case, EPA believes the person contracting with the manufacturer is the most knowledgeable party and should be responsible for submitting the notice. EPA recognizes, however, that the actual manufacturer will often have extensive information that would be useful to EPA in its review of the new chemical. Therefore, EPA strongly encourages joint submissions (see § 720.40(e)) in this situation. Since both persons involved in the transaction are manufacturers, both are liable for the manufacture of the new chemical if a notice has not been submitted, or the review period has not expired.

EPA did not adopt the proposed requirement that manufacturers of new chemicals solely for export submit notices under section 5(a) of the Act. ("Manufacture solely for export" is defined in § 720.3(s) of the rule.) Instead, EPA will soon propose that manufacturers of chemicals solely for export submit notices to EPA under section 8(a) prior to manufacture. EPA eliminated the requirement that manufacturers of new chemical substances solely for export submit a section 5 notice in response to comments that questioned EPA's legal authority to require such reporting. These comments will be addressed more fully in the preamble to the proposed section 8(a) reporting rule for export-only chemicals.

The definition of "manufacture solely for export" places certain restrictions on domestic activity. The manufacturer of an export-only chemical may process it only at sites under the control of the manufacturer. Distribution in commerce is limited to the activities necessary to export the chemical. Also, the manufacturer of an export-only chemical may not use the chemical for any purpose, except in small quantities solely for research and development.

b. *Importers.* Under § 720.22(b) of this rule, persons who intend to import a new chemical substance for a commercial purpose are subject to section 5 notice requirements. This includes chemicals imported in bulk or as part of a mixture. Because it would be enormously difficult for an importer to determine the identity and Inventory status of each chemical substance in imported articles (e.g., automobiles), the rule does not require persons to submit notices on new substances imported as part of articles. However, new chemicals imported in containers used for transportation or for other purposes are imported in bulk, not as part of an article, and are subject to the notice requirements.

EPA has eliminated the separate importer notice forms; importers must now complete the general notice form. In their notices, however, importers are required to provide information only on exposure which occurs within the United States.

In the January 1979 proposal and in § 720.3(1) of this rule, EPA defines importer to include the person primarily liable for the payment of duties, the consignee, the importer of record, the actual owner, and any transferee. This definition, which is adopted from the definition of the U.S. Customs Service of the Treasury Department, is consistent with other definitions of importer issued under the Act.

Several commenters on the January 1979 proposal suggested that EPA's definition of importer did not adequately indicate which party in an import transaction was responsible for submitting a section 5 notice. In response to these comments, EPA clarified importer reporting responsibilities under section 5 in the **Federal Register** of September 23, 1980 (45 FR 63806). This clarification has been incorporated into the final rule in § 720.3(z) and § 720.22(b).

Under § 720.22(b), the "principal importer" in any transaction leading to the import of a new chemical substance must submit a section 5 notice. The principal importer is the first importer who selects the new chemical substance and determines the total amount to be imported. The principal importer must know that the substance will be imported, and only a person incorporated, licensed, or doing business in the United States may submit the notice. Occasionally, no one person may fit this definition exactly. In this case, the Prenotice Communications Coordinator should be contacted to determine the appropriate person to submit the notice. Otherwise, the incorrect party may submit the notice, and the notice review period will not begin to run until EPA determines who should have submitted the notice and that person actually submits it. Early consultation with the Prenotice Communication Coordinator will avoid this delay. If import of a new chemical substance occurs before the principal importer submits a notice and the review period expires, all importers involved in the transaction are liable.

The following paragraphs further explain the definition of principal imported.

i. *Selecting the chemical substance to be importer.* The principal importer selects the new chemical substance for import. Selecting the substance to be imported includes selecting it by a trade name or generic name as well as by its specific chemical identity. Therefore, the principal importer need not know the specific chemical identity of the imported substance. If the specific chemical identity of the new chemical substance is known only to the foreign manufacturer or supplier, and the manufacturer or supplier does not wish to reveal the identity to the U.S. importer, it can report the identity directly to EPA. (See § 720.40(e) of the rule.) In this way, foreign companies can protect confidential business information. In any case, however, EPA must know the identity of the substance before the review period can begin.

Importers, like manufacturers, are responsible for determining whether their substances are on the Inventory and therefore whether they are new chemical substances subject to section 5 notice requirements. A principal importer that does not know the identity of a chemical substance it intends to import may have its foreign manufacturer or supplier, or some other person, report the chemical identity to EPA using the *bona fide* procedures described in § 720.25 of the rule. The principal importer would provide the evidence of a *bona fide* intent to import the chemical. EPA will then search the Inventory for the substance. If a notice is required, EPA will inform the importer. As a result, confidential chemical identity will be protected, and importers need not file unnecessary notices.

ii. *Knowing that the substance will be imported.* A principal importer must know that the new chemical substance will be imported into the United States, rather than manufactured domestically. If a person orders a new chemical substance directly from a foreign firm, EPA will consider that person to know that he or she is importing the substance. If a person orders a chemical from a U.S. firm and does not know and has no reason to know that the U.S. firm will fill the order by importing a new chemical, the person would not be subject to notification requirements or liable under section 15 for failure to submit a notice. In that case, the U.S. firm filling the order would be required to report.

iii. *Specifying the total amount to be imported.* The principal importer specifies the total amount of the chemical substance to be imported. If orders are collected from several customers, the person who collects the orders is the person who specifies the total amount to be imported and is subject to the notice requirements of this rule. Individual customers of the principal importer do not specify the total amount, even though one might have a disproportionately large order.

iv. *Incorporated, licensed, or doing business in the United States.* A principal importer must be incorporated, licensed, or doing business under the laws of the United States.

c. *Processors.* In August 1980, EPA proposed that persons be required to submit a section 5 notice to EPA before they processed for TSCA commercial purposes substances previously exempt from reporting. Specifically, this applied to byproducts; tobacco and tobacco products; nuclear materials; substances used solely as pesticides, firearms, ammunition, foods, food additives, drugs, and cosmetics; substances manufactured before January 1, 1975, and not processed and reported for the Inventory after that date; research and development (R and D) chemicals; and substances granted test-marketing exemptions.

EPA proposed processor notification requirements to close a gap in section 5 rules. EPA recognized that not many chemicals would be subject to notification requirements under this portion of the rule; however, EPA saw a need to review the risks associated with the processing and use of previously exempt substances for TSCA purposes before these activities occurred.

Persons who commented on the proposal argued that the requirement was unnecessary for R and D and test-marketed substances. They argued that manufacturers of test-marketed substances know how persons who buy the substances are using them because this information is necessary to make sure they are in compliance with the terms of the particular exemption. Also, manufacturers of R and D chemicals often know how their customers are using these chemicals. Therefore, EPA has eliminated the processor notification requirement for R and D and test-marketed substances. Of course, if a company that manufactures or imports a chemical for R and D or test-marketing purposes learns that its customer is using the chemical substance for nonexempt commercial purposes, manufacture or import of the chemical substance for sale to that customer for that purpose must cease until a section 5 notice is submitted and the review period expires.

EPA now also believes processor notification is inappropriate for nuclear materials, tobacco, and tobacco products because these substances are exempt from TSCA, regardless of how they are used. In addition, EPA believes that notification by processors of pesticides for nonexempt commercial uses is unnecessary because the uses of registered pesticides are regulated under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Of course, if a person intends to manufacture a pesticide for nonpesticide uses, these uses would not be subject to FIFRA. However, in this case, the manufacturer would be required by the statute to notify EPA under section 5(a)(1)(A) if the substance were not on the Inventory.

EPA also believes that notification for the processing of food and food additives for nonexempt purposes is unnecessary. These substances will already have been approved for human ingestion by the Food and Drug Administration (FDA). FDA also has jurisdiction over cosmetics and devices, as defined by the Federal Food, Drug, and Cosmetic Act. Therefore, EPA believes that notification by processors of food, food additives, and cosmetics is unnecessary, especially since persons would still be required under section 5(a)(1)(A) to notify EPA before they manufactured these substances for nonexempt uses.

Finally, EPA believes that processor notification requirements are unnecessary for the nonexempt processing of byproducts which have no separate commercial purpose. As is true of R and D and test-marketed substances, the manufacturer of a byproduct is expected to know of any nonexempt uses planned by its customer. In such cases, the byproduct would then be manufactured for a commercial purpose and the manufacturer would be required to submit a notice. Notification requirements are also unnecessary for nonexempt processing of substances which have not been manufactured since January 1975, since such processing rarely occurs.

Based on public comments and its reevaluation of the proposal, EPA now believes that processor notice requirements are unnecessary. Therefore, EPA has not included these requirements in the final rule.

d. *Agents and joint submitters.* Under § 720.40(e) of the rule, persons required to submit a section 5(a) notice may designate an agent to submit the notice for them. Both the person originally subject to the notice requirements and the agent must sign the certification on the form. Therefore, both persons are responsible for false or misleading statements in the notice. The person originally subject to the notice requirements remains responsible for the submission to EPA of all required information known to or reasonably ascertainable by him or her and all test data in the person's possession or control.

Persons may also submit joint section 5(a) notices to EPA. For example, a principal importer may ask other parties in the U.S., such as customers, to complete certain sections of the form if they have relevant information. All persons submitting the notice must sign the certification on the form. They must also assert all confidentiality claims according to the procedures of this rule. However, the person responsible for the notice under section 5(a) is not absolved of statutory notice requirements by arranging a joint submission. This person is required to complete all mandatory sections of the form, to the extent that he or she knows or can reasonably ascertain the required information, even if another person also submits a certain section. If a joint notice is submitted, the notice review period will not begin until EPA has received all required parts of the notice. Therefore, the person subject to the notice requirements should indicate to EPA who else will be submitting parts of the notice and identify those parts. EPA will acknowledge receipt of the notice when it has received submissions from all of the joint submitters.

2. *What chemical substances must be reported.* Section 5(a)(1)(A) of the Act requires persons to notify EPA before manufacturing or importing any new chemical substance, except for substances exempt under section 5(h). New chemical substances are chemical substances not included in the TSCA

Chemical Substance Inventory compiled and updated under section 8(b).

Under section 3(2) of TSCA and § 720.3(e) of the rule, chemical substances are defined as any organic or inorganic substance of particular molecular identity, including any combination of such substances occurring in whole or in part as a result of a chemical reaction or occurring in nature, and any element or uncombined radical. However, the following substances are excluded from the TSCA definition of chemical substance: mixtures; tobacco and tobacco products; nuclear materials; firearms and ammunition; and substances used solely as pesticides, foods, food additives, drugs, and cosmetics.

Manufacturers and importers are responsible for determining whether a substance is a new chemical substance under TSCA and therefore whether they are subject to section 5 notice requirements. The published Inventory will enable persons to determine whether many specific chemical substances have been entered on the list and therefore are not new. However, in difficult cases, EPA will assist persons in ascertaining whether specific substances are on the Inventory.

If a chemical substance is listed on the public Inventory under a generic name to mask its confidential identity, persons will not be able to determine if a specific substance falling into that category is a new chemical substance. Therefore, under § 720.25(b) of the rule, EPA has established procedures for informing persons whether a substance they intend to manufacture or import is a substance on the confidential Inventory, or whether it is a new substance subject to the section 5 notification requirements. Under these procedures, persons requesting this information from EPA first must demonstrate a *bona fide* intent to manufacture or import the substance by submitting the items listed in § 720.25(b)(2). These items have not changed from the proposed rule, except that the person need not have a sample of the substance available. EPA has found that samples are unnecessary to establish a person's intent to manufacture or import the chemical or to determine whether the chemical substance is on the Inventory. If an importer cannot provide certain requested items related to chemical identity because its foreign manufacturer or supplier claims them confidential, the importer can request the foreign manufacturer or supplier to send them directly to EPA.

EPA will respond to these inquiries within 30 days of receipt of a complete request. If the Agency determines that a substance is not on the Inventory, it will notify the person submitting the *bona fide* inquiry that a section 5 notice must be submitted before the substance is manufactured or imported. If EPA determines that the substance is on the Inventory, it will inform the person that a notice is not required. At the same time, EPA will inform the person who originally submitted the confidential substance for the Inventory that another person has demonstrated a *bona fide* intent to manufacture or import the substance and has been notified that the substance is on the confidential Inventory.

3. *Exempt chemical substances.* Section 5(h) of the Act exempts, or authorizes EPA to exempt, certain chemical substances from section 5 notice requirements. In §§ 720.36 and 720.38 of this rule, EPA clarifies several of these exemptions. The sections have not been substantively changed from the corresponding sections of the January 1979 proposal. The most important of the exemptions are discussed below.

a. *Small quantities solely for research and development.* Chemical substances manufactured or imported only in small quantities solely for research and development (R and D) are exempted from section 5 notice requirements if the submitter complies with § 720.36 of this rule.

Like the Inventory reporting rules, this rule defines "small quantities solely for research and development" as quantities that are not greater than reasonably necessary for scientific experimentation, research, or analysis (including activities associated with product development). As the Inventory rule and support documents indicate, research and development activities include tests of physical, chemical, production and performance characteristics. The chemical must be used by, or directly under the supervision of, a technically qualified person. The manufacturer or importer must evaluate information on the chemical and inform all persons engaged in experimentation, research, or analysis on the new chemical substance of any risk to health.

The section 5 notice rule deletes a note included in the Inventory definition. The note provided that, for purposes of the Inventory, any substance manufactured, imported, or processed in quantities of less than 1,000 pounds a year would be presumed to be manufactured solely in small quantities for R and D, unless the submitter could certify that the substance was used for purposes unrelated to R and D.

This note was intended to provide guidance for manufacturers in evaluating low volume chemicals to determine whether they were eligible for the Inventory. If the note were included in the section 5 notice rule, however, it might be misconstrued to mean that section 5 notices are not required for any substance produced in quantities of less than 1,000 pounds a year, or that section 5 notices must be submitted for all substances produced in quantities greater than 1,000 pounds a year. This deletion does not change the R and D exemption of the Inventory reporting rule, but it eliminates a possible source of misunderstanding about how substances qualify for such exemptions. In the future, the Agency may clarify the R and D exemption by establishing a more precise definition of "small quantities" for specific substances or groups of substances.

The final rule makes clear the manufacturer's responsibility under section 5(h)(3) to ensure that certain persons are notified of any risk to health that the manufacturer believes may be associated with R and D activities on a substance. This notification must go to all persons engaged in experimentation, research, or analysis on the substance, including manufacture, processing, use, transport, storage, or disposal of the substance for research and development purposes. The technically qualified individual supervising the R and D activities must ensure that the notice to these persons is adequate. The rule does not prescribe methods of notification. Rather, it identifies certain acceptable procedures, and leaves it to the individual manufacturers or importers to ensure that they adequately inform all the persons who must be notified.

Section § 720.36(d) states that, upon request, manufacturers and importers must make available to EPA any information evaluated by the manufacturer or importer in determining the need for notification. This provision differs from § 720.38(d) of the proposed rule which would have required the manufacturer or importer to make this information available to any person exposed to the R and D substance, as well as EPA. EPA has dropped this requirement because it reduces the burden on manufacturers or importers since making this information available to persons exposed to the R and D substance often would require preparation of nonconfidential summaries, and possible disclosure of sensitive information such as medical records. This change will not endanger the health of exposed persons since they will be notified of any risk by the

manufacturer or importer. In addition, EPA will have access to this information, so it can ensure that the notification of exposed persons is adequate.

The R and D provisions apply to all substances manufactured or imported after the effective date of the final rule, including substances manufactured or imported earlier under the R and D exemption. Therefore, persons that have been manufacturing or importing a chemical under a R and D exemption before the effective date of the final rule cannot continue to manufacture, import, process, distribute in commerce, use, or dispose of this chemical under the exemption until they have complied with all the requirements described in § 720.36.

b. *Test-marketing exemptions.* Section 5(h)(1) of TSCA and § 720.38 of this rule authorizes EPA, upon application, to grant exemptions from any requirements of section 5(a) or 5(b) of the Act for test-marketing purposes. To grant such an exemption, the Agency must find that the test marketing will not present any unreasonable risk of injury to health or the environment. Section 5(h)(6) and § 720.38(d) provide that EPA must either approve or deny the application within 45 days of its receipt and must publish a notice of its decision in the **Federal Register.** If EPA grants an exemption, it may impose restrictions on the test-marketing activities. The manufacturer or importer must submit a section 5 notice for activities beyond those permitted under the exemption.

In Unit II.B. of this preamble, EPA provides guidance to persons submitting test-marketing exemption applications and describes the information these applications should include.

c. *Nonisolated intermediates.* Under § 720.30(g)(8) of the rule, "any nonisolated intermediate" is not subject to the notice requirements. Intermediates are defined in § 720.3(n) as substances that are consumed in whole or in part in chemical reactions used for the intentional manufacture of other substances or mixtures, or that are intentionally present for the purpose of altering the rate of such reactions. Under § 720.3(w), a nonisolated intermediate is an intermediate that is not intentionally removed from the equipment in which it is manufactured.

This definition modifies the definition of intermediate in the Inventory reporting rule (40 CFR Part 710). Under the Inventory rule, substances that were not intentionally removed from the equipment in which they were manufactured were not considered intermediates and were not subject to the reporting requirements of the Inventory rule. In the section 5 notice rule, EPA has defined these substances as intermediates, but has exempted them from reporting requirements as "nonisolated intermediates." The change in definition is only for the sake of clarity, and does not change the status of these substances.

EPA is exempting nonisolated intermediates for several reasons. First, such substances are often extremely difficult to identify; in developing the reporting rule for the TSCA Inventory, EPA received numerous comments on this point. Second, because exposure to such substances generally is limited, they generally pose little risk to human health and the environment. Third, in excluding nonisolated intermediates from the Inventory, the Inventory reporting rule stated that these and other excluded substances will not be subject to the section 5 notice requirements. (See § 710.4(d).)

d. *Byproducts.* This rule expands the definition of byproduct contained in the Inventory rule to include substances which are formed without a separate commerical purpose during the processing, use, and disposal of the new chemical. Section 5(d)(1)(A) of the Act authorizes EPA to require information on such substances. This expanded definition is consistent with the definition of "byproduct" proposed in January 1979. Under both the proposed rule and the final rule, substances which were not eligible for inclusion on the Inventory are not subject to the section 5 notice requirements.

B. Information Submissions

1. *Scope of information requirements.* On January 10, 1979, EPA proposed notice requirements which included a notice form requiring reporting of detailed information on production, processing, use, and exposure of a new chemical substance. The mandatory section of the form was designed to give EPA enough information to conduct a detailed review for possible regulatory action under section 5(e) or 5(f). The form included an optional section, asking for information on industrial hygiene, engineering safeguards, and certain nonrisk factors. Based on public comments on the January proposal and EPA's early experience in reviewing notices, EPA reproposed a shortened form on October 16, 1979. This proposed form was designed to require only information needed for an initial assessment of a new chemical substance. Under both proposals, if EPA determined that it needed more information from the submitter or other persons, it could ask those persons to submit it voluntarily, or it could require the information through mandatory supplemental reporting under section 8 ("letter-writing" authority) or action under section 5(e).

In revising the information requirements for the final rule, EPA has considered the comments received on the previous proposals and EPA's information needs identified in its review of over 2,200 notices under the Interim Policy. The requirements are limited to (1) information clearly specified in the statute in sections 8(a)(2) (A) through (G) except (E), and (2) other information that is essential to the initial review of the potential health and environmental risks presented by a new substance and which reasonably falls within the intent of section 5(d)(1).

This rule further reduces the information requirements from those of the October 1979 proposal. Several commenters on the October 1979 proposal stated that EPA failed to require information identified in the January 1979 proposal as necessary for review of the risks associated with new chemicals. EPA agrees that much of this information can be important in the review of a new chemical substance. However, the Agency does not believe it is reasonable to require all such information for every substance reviewed under section 5 since EPA has found that detailed information is necessary only after it identifies a specific risk concern. The information required on the final notice form is sufficient for EPA to identify substances of potential concern and to determine what additional information is needed in those cases for which more detailed review is necessary.

Under the Interim Policy, EPA has contacted submitters during the review period and requested that they supply additional information when this information was important for its review. Submitters have been generally cooperative in providing the information. In developing this rule, EPA has assumed that such cooperation will continue in the future. Failure to supply such information when it is important to the review may unnecessarily complicate the review, and may result in extension of the review period under section 5(c). If EPA does not receive the information it believes is necessary for review, it will take action under section 5(e), when appropriate, to regulate the substance pending submission of the information.

Notice submitters must provide all information requested in the form to the extent that they know or can reasonably ascertain it. Submitters are also required to provide test data in their possession

or control and descriptions of other data known to or reasonably ascertainable by them, if those data concern the environmental or health effects of the substance. These requirements are described in more detail in the following sections. In addition to required information, submitters may provide EPA with any other information they believe should be considered in its review of the substance. The notice is incomplete, and the review period will not begin, unless information in the notice form and attachments is in English, except that published scientific literature submitted with the notice need not be translated.

The Importer Form proposed in October 1979 has been incorporated into the general notice form resulting in a single form that will be used by all submitters reporting under section 5(a)(1)(A). This change will simplify notification for submitters since they will have to become familiar with only one form and there will be no confusion as to which form should be submitted. EPA recognizes that some importers may not have the same amount of information available to them as domestic manufacturers. Importers, just as domestic manufacturers, need only submit information specified on the form to the extent that they know or can reasonably ascertain it. Importer notices, however, will be held to the same standard as domestic notices in determining whether the notice is complete or whether action under section 5(e) is necessary to obtain additional information.

The units below discuss the level of detail required in completing the form, and other general issues.

a. *Known to or reasonably ascertainable by.* Section 5(d)(1)(A) of the Act requires that notices contain certain information on chemical identity, use, and exposure insofar as it is "known to the person submitting the notice or insofar as reasonably ascertainable." This rule defines known or reasonably ascertainable information as "all information in a person's possession or control, plus all information that a reasonable person similarly situated might be expected to possess, control, or know." In response to commenters who believed that the phrase "or could obtain without unreasonable burden or cost" is unclear, EPA has dropped this phrase from the definition. This is not a substantive change, however, since such information is included in "information that a reasonable person . . . might be expected to possess, control or know." Therefore under the new definition, just as it is in the proposed definition, cost and burden are factors in determining whether information is known to or reasonably ascertainable by the submitter.

Many commenters on the January and October proposals expressed difficulty in determining what information EPA considers to be "reasonably ascertainable." Specifically, they were uncertain about the effort that EPA expects them to make in obtaining certain types of information, and what would constitute an "unreasonable burden or cost." In two parts below—" Information From Other Persons" and "Test Data"—EPA discusses in more detail its interpretation of "reasonably ascertainable" in specific contexts. Also, in Unit C.1.c. below, "Incomplete Submissions," EPA briefly describes notices received under the Interim Policy that did not contain "reasonably ascertainable" information. However, EPA believes that it is not possible to define "know to or reasonably ascertainable" more explicitly.

Also, as discussed in the preamble to the October 1979 proposal, a detailed definition of "reasonably ascertainable" may result in inequitable treatment of notice submitters. What would be a reasonable effort for one company under certain circumstances might be extremely burdensome for the same company under different circumstances, or for another company in the same situation. The meaning of this phrase will depend on the specific circumstances surrounding the development of the new chemical. The nature of the substance, the projected sales volume and profit, and the size of the company are factors in determining what information can reasonably be obtained. Therefore, EPA believes that "reasonably ascertainable" can be defined only on a case-by-case basis and that notice submitters must be responsible for deciding when and how to obtain required data, and when required information is not reasonably ascertainable. Certainly, in most instances, data-gathering that is so costly as to preclude commercialization is not reasonable.

To minimize the burden on submitters, EPA has dropped the provision in the proposed rule that would have required submitters to provide a brief description of their procedures for identifying data that are known to or reasonably ascertainable by them. EPA believes this provision is unnecessary; EPA generally can judge from the notice itself whether it includes information that is known to or reasonably ascertainable by the submitter. EPA will also check this as part of its compliance inspections.

b. *Information from other persons.* In many cases, persons other than the notice submitter may have information necessary or useful for EPA's review. For example, processors and other customers may have information on exposure associated with use or release, and foreign manufacturers and suppliers may have information on chemical identity, impurities, and health and safety data. Some of this information must be submitted because it is considered to be in the submitter's possession or control, for example, information that the submitter's parent company or subsidiary has if the related company was involved with R and D, test marketing, or commercial development of the new chemical. Other information may be reasonably ascertainable by the submitter, if not already known, and therefore also must be included in the notice.

EPA, however, has not adopted the requirement proposed in January 1979, that submitters contact customers and ask them to submit a Processing and Consumer Use Form. EPA also has eliminated the request in the October 1979 form that submitters report the number of customers intending to use the new chemical substance in ways not known to the submitter and to report the percentage of production volume allocated to those customers during the first three years of production. The form does, however, ask submitters to estimate how much of the substance will be manufactured or imported for each known category of use.

EPA has eliminated mandatory customer contact because information from processors and other customers often is not necessary for substances that do not undergo detailed review. EPA has found that when this information is necessary, EPA reviewers can generally obtain it either informally from the submitter or from the published literature. Submitters, however, are still encouraged to obtain use and exposure data from potential customers for inclusion in the notice. The more complete the information in a notice, the less likely it is that EPA will need to seek more information later, possibly requiring an extension of the review period under section 5(c), or regulatory action to obtain information under section 5(e).

The elimination of mandatory customer contact will reduce the burden on submitters and their customers without significantly reducing the effectiveness of EPA's review. By requiring the submitter to estimate how

much of a substance will be manufactured for known uses, EPA will be able to determine whether processing and use are likely to cause a problem, or whether more information is needed.

In the final rule, EPA has also eliminated the requirement that importers contact foreign manufacturers and suppliers, since much of the information they could provide (e.g., exposure to workers and release to the environment outside the U.S.) is not subject to EPA's review, and EPA generally does not have the authority to require foreign companies to report. More importantly, EPA believes that under the notice requirements in the final rule, the principal importer will contact its foreign manufacturer or supplier when necessary to obtain required information. For instance, if the principal importer does not know the specific identity of the new substance, it will contact the foreign manufacturer to obtain it; otherwise, the submission will be incomplete and EPA will not review it. Of course, the principal importer is encouraged to have its foreign manufacturer or supplier submit any other information useful for review to the importer or directly to EPA.

c. *Test data and other data.* Section 720.50 of the rule describes notice requirements for test data and other data related to the health and environmental effects of a new chemical substance. Under section 5(d)(1)(B) of the Act, submitters must report all test data related to health and environmental effects which is in their possession or control. Under section 5(d)(1)(C), they must provide a description of "any other" health and environmental effects data which they know of or can reasonably ascertain.

Health and environmental effects data on both the new chemical substance and related substances are necessary for an effective evaluation of risks that may be presented by a new substance. Therefore, the requirements to submit data apply to both the new chemical substance and related chemicals. Related chemicals include impurities, byproducts, degradation products, unintended reaction products, and other chemical substances related to the manufacture, processing, distribution in commerce, use, or disposal of the new substance.

To eliminate unnecessary reporting, § 720.50(c) imposes lesser requirements for data on related chemicals than are imposed for data on the new substance itself. Unlike the October 1979 proposed rule, the final rule does not limit the reduced requirements to related chemicals on the Inventory. Instead, they apply to all related chemicals, regardless of their Inventory status. The submitter is not required to provide published data on these substances because EPA can obtain the data elsewhere, regardless of whether or not they are on the Inventory. Therefore, submitters need only describe unpublished data on related chemicals.

i. *Definition of test data.* Section 720.3(gg) defines "test data." Tests, in EPA's definition, include both formal and informal tests and experiments. However, EPA no longer includes recorded observations, monitoring, or measurements as "tests"; instead, these would be "test data" if they were obtained in the course of a test or experiment. EPA believes this change more closely reflects the general understanding of these terms. Test data also include objectives, experimental methods and materials, protocols, results, and data analyses of tests and experiments, as well as raw data and other information relevant to the development and analysis of the data.

In the January 1979 proposal, the definition of "test data" included risk assessments. The final rule eliminates this provision, since EPA no longer believes that an analysis of the risk presented by the combined effects of hazard and exposure is described by the word "test." EPA has also eliminated the word "study" from the final definition of "test data" for the same reasons. Risk assessments are more appropriately included within the term "health and safety study," which is defined in § 720.3(k). EPA has added risk assessments to the examples of health and safety studies listed in § 720.3(k)(2).

In addition to reflecting more adequately the use of the term "test data" in the Act, the new definition will reduce the burden on submitters. Since risk assessments are now "other data" under the final rule, not "test data," submitters need only describe risk assessments which are known or reasonably ascertainable. Under the proposal, submitters were required to provide copies of all risk assessments which were in their possession or control.

The new definition of "test data," and the reduced reporting requirements which result, will not significantly affect EPA's ability to review the risk presented by new substances. If a risk assessment described by the submitter is needed for review, EPA will ask the submitter to provide it voluntarily. If the submitter does not provide it, EPA may extend the review period or take action to obtain it under section 5(e) of the Act.

ii. *Notice requirements for test data.* Section 720.50(a)(2) of the rule requires submitters to provide full reports on test data in their possession or control that are relevant to the health and environmental effects of the manufacture, processing, distribution in commerce, use, or disposal of the new chemical substance. These include data on the new chemical substance in pure form, technical grade, and formulated form. The rule requires a full report to be submitted for data on health effects, ecological effects, environmental fate characteristics, monitoring data, and physical and chemical properties related to health and environmental effects.

A full report must include experimental methods and materials, results, discussion and data analyses, conclusions, references, and the name and address of the laboratory that developed the data. EPA has dropped the requirement that the submitter provide data in a specified "full report format"; any format is acceptable if it includes the items listed. If the test data have been published in the open scientific literature, § 720.50(a)(3)(ii) authorizes submitters to provide only a standard literature citation. This provision reduces the requirements of the January 1979 proposal, which allowed submitters to cite articles containing test data only if the periodical in which the articles appeared was listed in Appendix I of the proposed form. Any other test data in the submitter's possession or control may be submitted in summary form. However, the submitter must provide a full report upon request by EPA.

Sections 720.50 (a)(4)(i) and (b)(4) of the rule exempt incomplete reports (e.g., from ongoing studies) from the full report requirements. However, submitters must describe the nature and objective of any incomplete study, report, or test; name and address of the laboratory developing the data; progress to date; types of data collected; significant preliminary results; and anticipated completion date. In addition, if the study or report yields significant preliminary or final results before the end of the notice review period, and if the results were not submitted with the notice, the submitter must provide the relevant study, report, or test results to the OTS Document Control Officer within 10 days of receipt; but in no event later than 5 days before the end of the notice review period. If the information becomes available during the last 5 days of the review period, the submitter must immediately inform its EPA contact for that notice by telephone. (See "New Information" below.)

iii. *Possession or control.* In the final rule, EPA has retained the definition of

"possession or control" proposed on January 10, 1979. Several commenters on the January proposal suggested that this definition would impose an undue burden on notice submitters, while others believed that EPA's definition did not go far enough. EPA, however, believes that its proposed definition is appropriate. Under this definition, the Agency is likely to obtain all relevant data without imposing an unreasonable burden. In particular, by limiting the definition to affiliated companies associated with the development of the new chemical substance, EPA has focused the information requirement on the companies most likely to have relevant data and to profit from the new substance. Comments on "possession or control" are addressed more specifically in EPA's Response to Comments, which is available in the Public Reading Room.

iv. *Other data known to or reasonably ascertainable by the submitter.* Section 5(d)(1)(C) requires submitters to describe "any other data," including data from health and safety studies, on health and environmental effects that they know or can reasonably ascertain. In § 720.50(b) of the rule, EPA interprets "any other data" to be (1) test data not in the submitter's possession or control but known to or reasonably ascertainable by the submitter, and (2) any data, other than test data, that the submitter possesses, controls, knows, or can reasonably ascertain. For example, if the submitter knows of toxicity or environmental fate data in the possession or control of another person, the submitter is required under section 5(d)(1)(C) and § 720.50(b) to describe those data to EPA. If the data have been published in the open literature, the submitter need only provide a standard citation. If the data have not been published, or the study is incomplete, the submitter need only describe the data and provide a summary of the results (if available), or provide the names and addresses of persons who have the data.

The final rule requires less information to describe data from incomplete studies than was required by the January 1979 proposal. EPA recognizes that information such as a study's nature and purpose, progress to date, and significantly preliminary results on another persons's ongoing study will seldom be available to the submitter. Also, as a result of the revised definition of "test data," discussed in Unit B.I.c.i. above, risk assessments are "other data" under the final rule, and must be described to EPA as required by § 720.50(b).

Section 720.50(b)(1)(ii) clarifies EPA's interpretation of "known to or reasonably ascertainable" as it applies to data submitted under section 5(b)(1)(C). In this context, known to or reasonably ascertainable includes data known to employees or other agents associated with research and development, test marketing, or commercial marketing of a new chemical substance. These data include data learned by employees as a result of discussions, symposia, and scientific articles.

v. *Data that need not be submitted.* Efficacy data and monitoring data on exposure of human or ecological populations outside the United States need not be submitted. In addition, persons are not required to resubmit any data previously submitted to EPA, as long as they were not claimed confidential. Submitters should identify the data previously submitted, the date it was submitted, and the EPA office which received it. However, it is sometimes difficult or time-consuming for the Office of Toxic Substances to obtain such information from other EPA offices in time to complete its review. Therefore, EPA encourages submitters to include all relevant information with the notice.

Relevant data previously submitted to another Federal agency must be included with the section 5 notice. This represents a change from the proposed rules which would not have required notices to include information already submitted to other agencies. EPA made this change because experience under the Interim Policy indicates that it is difficult to obtain information from other agencies in time to analyze and use it during the 90-day review period. EPA does not believe this change will be burdensome to submitters, since relatively few data described or submitted as part of section 5 notices have been previously submitted to other Federal agencies.

d. *New information or data.* During the notice review period, submitters may obtain additional information that may be relevant to EPA's review. Section 720.40(f) of the rule requires submitters to provide EPA with this information if it materially adds to, changes, or makes significantly more complete the information contained in the original notice. Examples of information that must be submitted under this provision include: preliminary or final results of health and environmental effects tests not previously known to the submitter, or not complete at the time of notice submission; new uses not described in the notice; significant increases in estimated production volume; new information significantly adding to information on chemical identity (e.g., significant changes in impurity levels, new information characterizing complex reaction products or polymers); and similar information.

The proposed rule would have required this information to be submitted to EPA "immediately." Commenters asked for more specific guidance on how long they would have to submit new information. The final rule now specifies that the information must be submitted within 10 days of receipt, but no later then 5 days before the end of the review period. If the information becomes available during the last 5 days of the review period, the submitter must telephone its EPA contact for the notice "immediately." EPA interprets this to mean as soon as possible, generally within 24 hours.

2. *Section-by-Section Review of the Notice Form.* The following paragraphs describe the major differences between the form proposed on October 16, 1979, and the final form issued with this rule.

a. *Submitter identification.* This section remains generally the same as in the October form. However, submitters are now asked to provide prenotice communication, *bona fide* request, and test-marketing exemption numbers to help coordinate the Agency's review. The parent company no longer must be identifed because the Agency believes that it can be obtain this information from the submitter during the review period in the few instances it is needed.

The form also eliminates the requirement that submitters state the intended date of commencement of manufacture or import and submit evidence of intent to manufacture if the intended date is more than 3 years after the date of the notice. EPA agrees with commenters that the submitter's certification on the form is sufficient evidence of intent to manufacture or import. However, EPA generally encourages manufacturers and importers to submit notices as close as is feasible to 180 days before manufacture or import is expected to begin, since early notices are more likely to have more complete information.

b. *Chemical identity.* For the most part, the requirements for information on the new substance's identity remain the same as in the October 1979 proposal. However, manufacturers and importers of new polymers must provide slightly different information than that specified in October. Instead of providing the range of composition of

each monomer in the polymer, manufacturers need only estimate the typical composition of the monomers and other reactants, e.g., catalysts and initiators. This information is necessary to evaluate fully the composition of the polymer. Submitters also must provide a representative structural diagram. The Agency has found that the majority of submitters have been able to develop such diagrams. To define further the composition of the new polymer, submitters must provide an estimate of the percent of the polymer composition below 500 and 1,000 molecular weight and describe how the estimates were made. The Agency believes that such information is essential to characterize fully the unique identity of the new polymer and its associated risks.

The rule requires that manufacturers provide at least one generic name for the substance, when chemical identity has been claimed confidential. EPA agrees with commenters that the requirement to provide three names, contained in the October proposal, is unnecessary, since the three names generally mask the identity of the substance to a similar degree. EPA encourages submitters to consult with EPA to develop a useful generic name before submitting the notice. If EPA determines that the generic name provided with the notice is inadequate, submitters will be required to develop a new name when the identity is added to the Inventory upon commencement of manufacture.

In general, the specific chemical identity of a substance is a critical element of the notice. If a submission does not adequately provide this information, EPA will determine that it is incomplete. If the submitter does not know the identity of a new chemical substance—for example, because it imports the substance under a trademark or makes it from unknown reactants—the submitter may authorize another person to report the specific identity or information that allows EPA to determine the identity. The submission, however, will be considered incomplete and the review period will not begin until EPA receives this information. For a discussion of incomplete submissions, see Unit III.C.1.e. below.

c. *Production and use information.* This rule requires reasonable estimates of the maximum production volume during the first year of production and the maximum 12-month production volume during the first 3 years of production. EPA believes that these projections provide sufficient information to perform its exposure assessment and economic analysis. The proposed rule would have required submitters to report both maximum and minimum projections for each of the first 3 years of manufacture. Since EPA's review of notices under the Interim Policy has typically focused on the first year production volume and anticipated maximum volume, more detailed requirements are not justified.

The final rule requires information on the intended categories of use of the new substance in a level of detail similar to that contained in the January proposal. However, it does not require that the submitter consult the standard use classification system developed by EPA for providing its use description. EPA believes that the general concepts of "function" and "application" provide an appropriate method of categorizing uses. A description of use in terms of the substance's chemical function and the general application of that function will provide EPA with sufficient information to identify the populations exposed to the new substance and the nature of that exposure. The submitter also must provide the estimated percent of production volume devoted to each category of use.

Many commenters stated that EPA does not have the authority to require information beyond the broadest category of use (e.g., surfactant, photographic chemical) or that use information, at the level of detail required, is not typically known by the manufacturer. EPA disagrees. The category of use description required under these rules is consistent with the general intent under section 5(d)(1) to provide EPA with the information necessary for review. Adequate information on the use of a substance is critical in the evaluation of the potential risks associated with human exposure to and environmental release of the new substance in that use. EPA has found that the information required in this section is the minimum necessary to conduct a review of such risks. In addition, EPA has found that such information is available to the great majority of notice submitters because substances are typically manufactured for a particular use.

Under section 5(d)(2) of the Act, EPA must issue the uses or intended uses of a new substance for publication in the Federal Register. EPA will publish the use as reported in the notice unless it is claimed confidential. Consistent with the Act's requirements and the October proposal, this rule requires manufacturers who claim use to be confidential to provide a nonconfidential (generic) use description which EPA can issue for publication in the Federal Register.

d. *Hazard information.* This rule retains the requirement to submit a copy or reasonable facsimile of any hazard information which will be provided to workers or customers, e.g., a Material Safety Data Sheet. Several commenters stated that hazard information is not required under section 8(a)(2). EPA believes that such information falls clearly within the requirements of section 5(d)(1)(C) of the Act since it provides data on the potential exposure and health effects of the new substance. Such information has been an important factor in EPA's evaluation of new substances under the Interim Policy.

e. *Transportation and detection methods.* EPA has eliminated proposed questions on transport and detection methods. Again, experience indicates that data in response to these questions is not especially useful in notice review.

f. *Human exposure and environmental release information.* EPA has retained the requirement that submitters describe the manufacture and processing operations involving the new chemical substance at sites they control. Commenters on the October proposal stated that providing this information would be unduly burdensome and might jeopardize the confidentiality of process information. However, in its review of notices under the Interim Policy, EPA has found the process description necessary to make qualitative estimates of potential workplace exposure, to estimate the amounts of the new substance and byproducts released, and to evaluate estimates provided in other parts of the form. EPA has also found that process descriptions based on known or reasonably ascertainable information may be developed by submitters in less time than was originally anticipated, and that OTS procedures adequately protect any confidential business information contained in the notice.

In response to these comments, however, the Agency has reduced the amount of information it will require in the process description from the requirement proposed in October. EPA does not require that a mass balance of materials entering and leaving major unit operations and chemical conversions be provided, nor must submitters report the methods of transfer of materials and whether the operations are open or closed to the workplace. Based on its experience under the Interim Policy, EPA has found that identification of major unit operations and chemical conversions, identity and mass of materials entering

the process, and points of release of the new substance is sufficient for its initial review and is information known to or reasonably ascertainable by submitters.

The sections of the form on occupational exposure to and environmental release of the new substance are largely unchanged from the October form. Instead of requiring the specific routes by which workers will be exposed, submitters need only identify the activities of workers. This more generic approach will still provide EPA with a more accurate indication of exposure potential. Submitters also are not required to provide estimates of the concentration of the new substance in the workplace because EPA can make such estimates from the process description to the extent necessary for its initial review. Submitters are now required to identify the type of control technology used to control environmental release since control equipment is frequently used and since manufacturers typically have identified the equipment that will be used by the time the notice is submitted. The final rule does not require estimates of the duration of release for each point of release. EPA will instead use reasonable estimates based on the duration of the process in its release analysis.

g. *Sites controlled by others.* The section on industrial sites controlled by others has been modified to require general information on the activities of customers who process and use the new chemical substance. Submitters must provide a narrative description of processing and activities focusing on those aspects which relate to the potential for human exposure and environmental release of the new chemical substance to the extent that they know or can ascertain this information.

The October proposal would have required submitters to provide the same quantitative estimates for sites controlled by others as for the sites which they controlled themselves. However, manufacturers typically do not have such detailed quantitative information on activities not under their control. Furthermore, the specific circumstances of customers' operations may vary, and all customers may not yet be known, so that it may be difficult to make quantitative estimates. The narrative description required in the form will provide sufficient information for EPA to evaluate potential worker exposure and environmental release at customers' sites for EPA's initial review, and allow identification of additional information needs where the Agency has identified a specific concern. In this case, EPA may contact the submitter or possible customers to obtain additional information.

h. *Consumer and commercial user exposure.* EPA has eliminated this section from the final form. Thus, manufacturer estimates of exposure that would result from commercial and consumer use of the new chemical substances or final products containing the new substance are not required. EPA intends to use the information provided in the "use" section of the form and other information, such as production volume, physical/chemical properties, and its own knowledge of typical commercial and consumer exposure scenarios, to evaluate commercial and consumer exposure. EPA's experience under the Interim Policy indicates that it can conduct such an evaluation where the submitter provides the information required in other sections of the form.

i. *List of attachments.* The list of attachments is generally the same as it was in the October form. For a discussion of test data requirements, see Unit III.B.1.c. of this preamble.

j. *Optional information.* The final form does not contain a detailed optional information section as was proposed in the January 1979 form. EPA believes such a detailed section may limit the information that might be submitted and, by identifying specific questions, may make optional information seem mandatory. The Instructions Manual describes generally those items in which additional information would be most helpful in EPA's review. For example, submitters may wish to provide information on relative risk, process chemistry, efficacy, additional exposure and environmental release information, industrial hygiene, engineering safeguards, use restrictions, and economic and other benefits of the new substance. Information in these areas may eliminate the need for extensive communication between EPA and the submitter during the review period and may reduce the possibility of an extension of the notice review period under section 5(c) or regulation under section 5(e) or 5(f). Although submitters are encouraged to submit optional information, they are in no way required to do so.

k. **Federal Register** *notice.* EPA has eliminated the section of the October form which requested information for the section 5(d)(2) **Federal Register** notice. Sections for generic descriptions of confidential chemical identity and category of use have been moved to other parts of the form. In compiling the section 5(d)(2) notice, the Agency will assemble the necessary information from the various parts of the notice. For a further discussion of generic descriptions, see Unit III.D. of this preamble.

l. *Confidentiality claims.* Submitters may assert claims of confidentiality for any information on the notice form and any attachments to the form, although they should note that under section 14(b), claims for information in health and safety studies will be denied unless disclosure would reveal process information, proportions of a mixture, or information unnecessary to interpret the study. (See Unit III.D.4) Instructions for making claims are given on the form. If chemical identity or use is claimed confidential, the submitter must provide a generic chemical name or generic use that is as specific as possible.

EPA no longer requires substantiation of confidentiality claims when the notice is submitted. However, any submitter that claims information confidential must supply two copies of the notice: One complete copy, and one "sanitized" copy with all confidential information deleted. EPA will put the sanitized copy in the public record. The notice is incomplete, and the review period does not begin, until EPA has received both the complete notice and the sanitized notice. EPA explains its confidentiality policy in more detail in Unit III.D. of this preamble.

C. Notice and Review Procedures

1. *Submission and Processing of Notices.*

a. *Acknowledgement of receipt.* Under § 720.65(a), EPA will acknowledge receipt of each notice by letter to the submitter. The 90-day notice review period begins on the date of receipt indicated on the letter of acknowledgement.

b. *Consolidated notices.* In the course of reviewing section 5 notices under the Interim Policy, groups of notices were often submitted for substances which were similar in structure and use. These notices contained a large amount of duplicative information, such as exposure, release, or use data. In response to requests for relief from submitters, EPA has developed procedures for submission of a "consolidated" notice. Persons who intend to manufacture or import two or more structurally related new chemical substances may contact the Prenotice Communications Coordinator to obtain approval to submit a single "consolidated" section 5 notice for the related substances. The submitter must identify each new chemical substance individually; a consolidated notice cannot be submitted for an open-ended

category of chemicals. A consolidated section 5 notice is suitable for chemical substances with the same or similar uses and for which there are similar test data or other information. Manufacturers may not submit a consolidated notice on a series of intermediates and a final product in a given process because these chemicals do not sufficiently share common test data or other information.

EPA will not accept a consolidated notice unless the submitter has contacted the Prenotice Communications Coordinator to determine whether the group of chemicals are sufficiently similar that they are suitable for review in a consolidated notice. EPA encourages submitters to submit consolidated notices when appropriate; such notices will reduce the burden on the submitter of preparing multiple section 5 notices sharing common information. Consolidated notices also will improve the efficiency and consistency of EPA's review by allowing the staff to review structurally related chemicals, and the data and other information that are common to them, at the same time.

c. *Incomplete submissions.* Under § 720.65(c) of this rule, EPA may determine that a submission is incomplete, and therefore does not constitute a notice under section 5 of the Act. For example, failure to provide chemical identity or otherwise to supply information required in the notice form, if that information is known to or reasonably ascertainable by the submitter, will result in a submission that does not constitute a notice. A submission is incomplete if all information (except information published in the scientific literature) is not in English or test data and other data are not complete. A submission is also incomplete if the submitter claims information confidential and does not submit a second copy of the notice from which all confidential information has been deleted. The review period will not begin until the submission is complete.

If a submission is incomplete, EPA may first request the missing information from the submitter by telephone. If the submitter does not provide it quickly, EPA will inform the submitter in writing within 30 days of receiving the submission that it is incomplete. However, if EPA obtains additional information during the notice review period, from the submitter or elsewhere, that indicates the original submission was incomplete, EPA may declare the notice incomplete within 30 days of receiving the new information.

Under § 720.65(c) (4) and (5), submitters may file objections to an EPA finding that a submission is incomplete with the Director of the Office of Toxic Substances ("the Director"). The Director, or his or her delegate, will determine whether the original submission was complete or incomplete, or will modify the requirements for completing the submission. If the Director affirms that the original submission was incomplete, the notice period will not begin to run until EPA receives the missing information. If the Director finds that the original submission was complete, the 90-day review period will resume on the date that EPA notifies the submitter that the notice is complete. Therefore, if EPA informed the submitter that the notice was incomplete on the 15th day, the day after EPA finds the notice was complete would be the 16th day. However, if EPA can complete its review by the date 90 days from the date of the original submission, the Director may inform the submitter that the review period began when EPA received the original notice and has run without interruption. EPA recognizes that resuming the review period on the date EPA notified the submitter that the submission was incomplete may conceivably delay the start of manufacture or importation in some cases; however, EPA has an overriding responsibility to conduct an adequate review which ensures against a potential risk to human health or the environment. EPA will avoid delaying the starting date whenever possible.

If EPA identifies a minor problem in the submission, such as failure to date it or a typographical error that renders an entry ambiguous, it may, under § 720.65(b), ask the submitter to correct the notice. The submitter is under no obligation to make the correction, but failure to do so may cause EPA to extend the review period under section 5(c) of the Act. Of course, if the submitter corrects the minor problem, EPA may still extend the period under section 5(c) if good cause otherwise exists.

The final rule modifies the procedures for incomplete submissions proposed in January 1979. Under the proposed procedures, submitters had no formal appeal procedures if EPA determined that a submission did not meet the standards for review, and the review period for submissions with minor errors could be stopped until the errors were corrected. EPA has changed these requirements in response to comments and because of its experience under the Interim Policy.

EPA, however, disagrees with commenters who argued that EPA has no authority to determine that a submission is incomplete, and that EPA's only remedy is section 5(e). The Act explicitly requires the submitter to provide certain information in a section 5(a) notice that is known to or reasonably ascertainable by the submitter. A submission that fails to meet the minimum statutory requirements, therefore, is not a complete notice under the Act, and EPA is justified in refusing to review it. Section 5(e) is not an appropriate remedy for this situation. The purpose of section 5(e) is to allow EPA to regulate new chemical substances "pending the development of information" necessary for a reasoned evaluation of health and environmental effects. Its purpose is not to gather information that the submitter already knows or can reasonably ascertain and that is required by the Act to be submitted in the initial notice.

Under the Interim Policy, EPA has received several submissions that, it believed, did not include required information that was known or reasonably ascertainable by the submitter and which therefore did not meet the statutory requirements. For example, one submission did not include the molecular structure of the new chemical substance. EPA scientists determined that representative molecular structures for the substance were in fact known to or reasonably ascertainable by the submitter, because a knowledgeable chemist would be able to derive the structure from process information. Therefore, the notice review period did not begin until this information was provided to EPA.

In another case, the submitter described the category of use of a new chemical substance only as "photographic chemical" without specifying its end use in terms of its function and application (e.g., reducing agent in developer solution). The term "photographic chemical" was inadequate for EPA's assessment of potential human exposure and environmental release. In a third type of problem, submitters often have described the chemistry of the manufacturing operation without indicating the order and type (e.g., distillation, mixing) of the manufacturing steps. For example, manufacturers of coatings for manufactured parts have sometimes failed to provide information on coating operations at sites they do not control. In such cases, if EPA staff cannot quickly obtain the information from the submitter in response to a telephone request, EPA will declare the notice incomplete and the review period will not begin until EPA receives the information.

d. *Extension of review period.* Section 5(c) of the Act provides that EPA may extend the 90-day review period for up to an additional 90 days for good cause. Section 720.75(c) of this rule provides that EPA will notify the submitter if EPA extends the period and gives examples of circumstances that EPA believes could constitute good cause for extension. EPA will also issue for publication a **Federal Register** notice when it extends a review period under section 5(c). The notice will describe the extension and give the reasons for it.

e. *Suspension of review period.* Section 720.75(b) of this rule provides that a notice submitter may voluntarily suspend the running of the review period at any time, but only if the Director, or his or her delegate, agrees. If the Director does not agree, EPA will notify the submitter and the review period will continue to run. The suspension must be for a specified period of time. If the notice submitter makes the request orally, the Director may grant a suspension for 15 days. EPA will send the submitter a written confirmation of the suspension if it is granted orally. The Director will extend the suspension if the OTS Document Control Officer receives a written confirmation of the request within 15 days of the approved oral request. In this case, the running of the review period is suspended as of the date of the confirmed oral request. The notice submitter also may request a suspension in writing. In this case, the suspension begins the date the Document Control Officer receives the request, if EPA approves the request.

Under the Interim Policy, EPA has found suspension of the review period may be beneficial when questions concerning a new chemical substance that arise during the notice review period can be adequately addressed by the notice submitter. Suspension of the review period is often helpful in these cases because a submitter may not be able to respond to EPA's concerns within the review period, even if EPA extends the period to 180 days under section 5(c). For example, in one instance the Agency needed more detailed use and exposure information which the submitter was able to obtain from potential customers. In other cases, the notice review period was suspended to allow time for voluntary health effects testing, and for chemical analysis to determine the levels of certain impurities. Voluntary suspensions benefit both EPA and notice submitters because they save EPA resources and often eliminate the need for regulatory action.

f. *Closeout and commencement of manufacture.* Under § 720.75(d), EPA will notify submitters when the notice review period has ended, if EPA has not taken action under section 5(e) or 5(f) of the Act. EPA will inform submitters that they can begin manufacture or import for commercial purposes. This action does not constitute EPA approval or certification of the substance and does not preclude later regulatory action by EPA. Submitters may begin to manufacture or import a new chemical substance after the close of the review period, even if they have not been notified by EPA that the review period has ended. In the final rule, EPA has dropped the notice of continuing review proposed in January 1979, since the closeout notification can serve the same purpose, i.e., informing the submitter of any concerns EPA may have about the new chemical substance, and any regulatory actions being considered. Also, there is no obligation that EPA inform a submitter that it is contemplating regulation of the new chemical substance.

Section 720.102 requires that submitters notify EPA when they begin to manufacture or import the new chemical substance, so EPA may add the substance to the Inventory. The submitter must provide chemical identity, premanufacture notice number, and the date that manufacture or import for commercial purposes begins. EPA proposed this requirement in January 1979 and believes that most notice submitters to date have notified EPA when they began manufacture or import. However, any persons who already have begun to manufacture or import a chemical substance after undergoing notice review, but who have not yet submitted a notice of commencement or manufacture, must submit the notice by the effective date of this rule to allow EPA to update the Inventory.

2. *Supplemental Reporting.* In January 1979, EPA proposed supplemental reporting ("letter-writing") authority which would have enabled EPA to obtain additional written information on a new chemical substance or related chemicals during the notice review period. EPA also proposed an analogous provision for requesting health and safety studies. EPA based its authority to obtain certain information known to or reasonably ascertainable by the submitter and others on section 8 of the Act. Even after the scope of reporting was narrowed in the October 1979 reproposal, many commenters objected to the supplemental reporting provisions, arguing that EPA does not have authority to require such reporting.

Since the reporting requirements in the final rules are reduced from those in the proposed rules, the ability of EPA to obtain additional information during the review period is especially important. While EPA still believes it has the authority under section 8 to obtain additional information from the submitter and others who may have information about the new chemical substance during the notice review period, EPA has not adopted supplemental reporting authority because it has proved unnecessary to an effective section 5 notice review program. EPA also has eliminated the provision for requesting health and safety studies on the new chemical substances or related chemicals. EPA has found that telephone calls to submitters are generally adequate to obtain additional information during the notice review period. In the occasional case where a submitter is unwilling to provide the information, EPA has the option of taking action under section 5(e) (regulation of a new chemical substance pending development of new information) or section 11 (subpoena authority). Although these actions are more resource-intensive and time-consuming than a supplemental reporting request, such formal actions will rarely be necessary. However, EPA is prepared to act under these authorities when submitters do not provide the necessary information.

3. *Actions Under Sections 5(e) and 5(f).* In the final rule, EPA has deleted §§ 720.36 and 720.37 of the January 1979 proposal, which described EPA's procedures for taking action under sections 5(e) and 5(f). It is not necessary to include these provisions in the rule, because many of the procedures are already set out in the statute, and because submitters will be notified of the remaining procedures when EPA takes action against a specific substance. In dropping these sections, EPA has deleted the provision that would allow it to notify persons other than the notice submitter, who would be affected by the order, of the basis of a proposed section 5(e) or 5(f) action. Many commenters objected to this provision, arguing that only the notice submitter could be subject to a section 5(e) or 5(f) order. EPA will notify only those persons subject to a section 5(e) or 5(f) order, and it will allow only those persons to file objections to the order. Of course, any person who uses a new chemical substance that the person knows or has reason to know was manufactured, imported, processed, or distributed in commerce in violation of a

section 5(e) or 5(f) order is in violation of section 15 of TSCA.

EPA has also eliminated § 720.37(b)(6) of the January 1979 proposal, which provided that EPA would consider subsequent notice submissions for substances subject to a section 5(f) order to be applications for modification or revocation of the order, rather than section 5 notices. This section was eliminated because EPA recognizes that a subsequent submission for a chemical substance subject to a section 5(f) order might describe different conditions of exposure which might not present an unreasonable risk. Therefore, EPA will consider these submissions to be section 5 notices, and they will undergo review.

4. *Recordkeeping.* The final rule retains the provision in the proposed rule that requires notice submitters to retain documentation of information in the notice. This would include the sources of information provided in the notice, e.g., production volume estimates in marketing plans. Submitters also must keep records of production volume for the first three years of production and the date of commencement of manufacture or import, and documentation of this information. In addition, submitters must keep copies of "other data," which they were required to describe in § 720.50(b), if they are in the submitter's possession or control. This information must be retained for 5 years from the date of commencement of manufacture.

EPA has dropped the provision that the submitter retain health and safety data referenced in the notice for 30 years. EPA believes this provision is unnecessary because the submitter must include these data, or a standard literature citation to these data, with its notice. Therefore, EPA will already have the data in its own files.

Persons who manufacture or import a chemical substance under the terms of an R and D exemption must retain documentation of compliance with the exemption requirements, including copies of the information they used to determine the need to make any notification of risk to health or to persons exposed to the chemicals. This information must be retained for 5 years from the final date of manufacture or import under the exemption.

Persons who are granted a test-marketing exemption application must retain documentation of information submitted in the notice. They also must document compliance with any restrictions EPA imposes when it grants the exemption. This information must be retained for five years from the final date of manufacture or import under the exemption.

5. *Compliance and Inspections.* It is unlawful for any person to fail or refuse to comply with any provision of section 5 or any rule promulgated under section 5. Manufacture or processing of new chemical substances without complying with section 5 and this rule is a violation of section 15. When more than one manufacturer or importer is involved in a transaction, each one is liable for manufacture or import of a new chemical substance if a notice has not been submitted or the review period has not expired, even though only one person involved in each transaction (e.g., the principal importer) may submit the notice.

Section 15 of TSCA makes it unlawful for any person to: (i) Use for commercial purposes a chemical substance or mixture which such person knew or had reason to know was manufactured, processed, or distributed in commerce in violation of this rule.

(ii) Fail or refuse to establish and maintain records or to permit access to or copying of records as required by the Act or a rule promulgated under the Act.

(iii) Fail or refuse to permit entry or inspection as required by section 11.

Violators may be subject to criminal and civil liability. Persons who submit materially misleading or false information in connection with the requirement of any provision of this rule may be subject to penalties calculated as if they never filed their notices. Under the penalty provision of section 16 of TSCA, any person who violates section 15 could be subject to a civil penalty of up to $25,000 for each violation. Each day of operation in violation could constitute a separate violation. Knowing or willful violations of this rule could lead to the imposition of criminal penalties of up to $25,000 for each day of violation and imprisonment for up to one year. Other remedies are available to EPA under sections 7 and 17 of TSCA such as seeking an injunction to restrain violations of the rule and the seizure of chemical substances manufactured or processed in violation of the rule.

Individuals as well as corporations could be subject to enforcement actions. Sections 15 and 16 apply to "any person" who violates various provisions of TSCA. Thus, in actions under section 16, EPA may, at its discretion, proceed against individuals, such as corporate officials, as well as the companies themselves. In particular, this includes individuals who report false information or who cause it to be reported.

EPA will also direct its resources to detecting violations of other aspects of the section 5 notice rule, particularly the terms of exemptions for research and development and for test marketing.

EPA will conduct inspections under section 11 of TSCA to assess compliance with the requirements of section 5 and this final rule. Inspectors will compare the information in the submitter's notice with the actual conditions of manufacture or import to verify that the information was correct, estimates were reasonable, and any exposure controls described in the notice are in place.

D. Confidentiality

The Act recognizes the importance to industry of maintaining the confidentiality of certain business information; section 14 allows a submitter to claim confidentiality for any information submitted to EPA under the Act. However, the Act also makes clear that the public interest in chemical regulation must also be considered, and in certain cases, outweighs the protection of confidential business information. Thus, section 14 also provides that health and safety studies may be revealed and that any confidential information may be revealed if necessary to protect health or the environment from an unreasonable risk of injury.

Certain provisions of section 5 also highlight EPA's responsibility to provide meaningful information to the public concerning new chemical substances. Section 5(d)(1) states explicitly that a section 5 notice must be made available for "examination by interested persons," subject to the confidentiality provisions of section 14. Further, section 5(d)(2) requires EPA to issue for publication a **Federal Register** notice upon receipt of each section 5 notice, that identifies the chemical substance, lists the intended uses, and describes test data, also subject to the confidentiality provisions of section 14. More generally, the Act includes a variety of provisions under which citizens can petition EPA to take particular actions on section 5 notices. These provisions indicate that Congress intended informed citizen involvement in review of new chemical substances, although EPA is to be the primary decisionmaker. Public participation cannot be effective unless meaningful information is made available to interested persons.

In addition to these responsibilities which are related directly to the Act, EPA has general responsibilities under the Freedom of Information Act (FOIA). Under the FOIA, persons may request disclosure of any information submitted in a notice. When such a request is made, EPA, in accordance with the

procedures of 40 CFR Part 2, Subpart B, must review information which is claimed confidential to determine whether it is entitled to confidential treatment. If EPA determines that the information is confidential and therefore does not disclose it, the FOIA requester may bring an action in Federal court to review EPA's decision.

The confidentiality provisions in the final rule take into account various requirements under the Act, including the need: (1) to provide nonconfidential information to the public, (2) to give EPA information it needs to respond to FOIA requests, (3) to allow persons to assert claims of confidentiality with the minimum burden, and (4) to reduce uncertainty about the criteria EPA will use in making its confidentiality determinations. In determining the final confidentiality provisions, EPA also considered its experience with section 5 notices under the Interim Policy as well as comments received on the January 1979 and October 1979 proposals. EPA believes these provisions represent a balance between the industry's need for confidentiality of business information and the public interest in having access to information about new chemicals.

1. *Assertion of Confidentiality Claims.* A person may assert a claim of confidentiality for any information submitted to EPA. Submitters must assert the claim when they submit the confidential information. If the information to be claimed confidential is contained on the notice form, submitters must assert their claims by marking the box on the form adjacent to the item. To assert a claim for information in an attachment to the form, submitters must clearly mark all confidential items in the attachment.

Any submitter that claims information confidential must provide two copies of its submission: a complete copy of the notice including all confidential information and a "sanitizied" copy in which all confidential information has been deleted. EPA will assume that the submitter has prepared a sanitized copy that accurately deletes any information claimed confidential. EPA will place the submitter's sanitized copy in the public file. If the submitter does not provide a sanitized copy, the submission is incomplete and the notice period will not begin. EPA believes this provision is in the best interest of the submitter, the public, and EPA.

Alternatively, if the submitter does not provide the sanitized copy with the notice, EPA could consider the submission complete and allow the submitter to provide the sanitized version early in the notice review period. However, this would deprive the public of access to the notice information for a significant portion of the review period. EPA could also prepare the sanitized copy itself. However, this would require substantial EPA resources and there is a chance that EPA inadvertently would not delete all of the information claimed confidential. In addition, EPA believes it is more efficient for the submitter, which is more familiar than EPA with the nature, extent, and rationale for the claims, to prepare the sanitized copy. EPA also considered the alternative of putting the entire notice, including information claimed confidential, in the public file if the submitter did not provide a sanitized version. However, EPA believes this would be unnecessarily harsh. Therefore, EPA believes that treating the notice as incomplete until it receives the sanitized version is the most equitable policy.

2. *Generic Information.* A submitter that claims chemical identity or use confidential must provide generic information for release to the public. By requiring generic chemical names and uses, EPA can meet its obligation to provide the public with important information on the risks of new substances without revealing confidential business information. EPA requires that the generic information be provided on the notice form so it can include this information in the section 5(d)(2) **Federal Register** notice. If EPA had to request the generic information after it received the notice, or develop the generic information itself, EPA could not meet the requirement that the **Federal Register** notice be published 5 days after EPA receives the notice form.

Unlike the proposed rule, the final rule does not state that the generic chemical name must disclose "toxicologically significant information to the maximum extent possible"; instead, the generic name should reveal the substance's chemcial identity to the maximum extent possible. EPA has found that, prior to a substantive review of the hazard potential of a new substance, it is often difficult to identify toxicologically significant portions of the molecule. Therefore, at the beginning of the notice review period, it is more useful to require instead that the chemical identity be revealed as fully as possible. The generic use should also be as specific as possible. EPA encourages submitters to contact the EPA Prenotice Communications Coordinator to discuss appropriate generic names and uses before actually submitting the notice.

The proposed rule would have required that submitters provide three generic chemical names with the section 5 notice; however, the final rule requires only one. EPA's experience in the section 5 program has shown that three names are not necessary since, generally, all three names provided are similar in specificity. EPA will publish the generic name given in the notice in the section 5(d)(2) **Federal Register** notice. However, when the manufacturer or importer submits a notice of commencement of manufacture using the same generic name, EPA may determine that the generic name is more generic than necessary to protect confidential chemical identity. EPA will then propose a more specific name. If that name is unacceptable, the submitter must explain why EPA's name would disclose confidential business information and propose an alternative. EPA will publish the submitter's alternative name if it is acceptable. Otherwise, EPA will put the generic name it devised on the public Inventory, 30 days after giving notice to the submitter.

EPA has not adopted the proposed requirement that submitters provide generic information on physical/chemical properties (in terms of ranges) and submitter's identity (in terms of geographic location, annual sales, and type of company) if they are claimed confidential. EPA made this change in response to commenters who stated that it is difficult to develop generic descriptions of physical/chemical properties and submitter's identity which provide useful information without disclosing confidential business information. Also, unlike chemical identity and category of use, EPA is not required to issue any information concerning physical/chemical properties or the submitter's identity for publication in the **Federal Register**. Therefore, generic information on these categories is not necessary.

3. *Substantiation of Claims.* The final rule does not require substantiation of any confidentiality claims when a section 5 notice is submitted. However, a confidentiality claim for chemical identity must be substantiated when the notice of commencement of manufacture is submitted.

This approach reflects a substantial modification of the confidentiality procedures proposed in January 1979 and October 1979. The January proposal would have required submitters to substantiate confidentiality claims at the time of submission only for chemical identity and health and safety data, while the October proposal would have required substantiation of all confidentiality claims at the time of submission (though it allowed assertion and substantiation by category.) EPA

believed that this "up-front" substantiation would be necessary to allow EPA to respond to FOIA requests in a timely manner.

Under the Interim Policy, submitters were encouraged to substantiate all confidentiality claims when the notice was submitted; if they did not substantiate their claims, EPA sent a letter requesting substantiation. EPA changed this policy in a notice published in the **Federal Register** of July 3, 1982 (47 FR 28969). In that notice, EPA explained that because EPA had not received large numbers of FOIA requests, "up-front" substantiation of claims was not necessary to make timely responses to FOIA requests. Also, the substantiation requirement had not reduced the number of confidentiality claims as expected. The final rule adopts the same policy. EPA will request substantiation for information submitted in section 5 notices only when it receives an FOIA request for the information claimed confidential, or when EPA has its own reasons for making a final confidentiality determination, for example, when EPA is contemplating regulatory action. By not requiring "up-front" substantiation of all claims, submitters will not have to incur the burden of substantiation unnecessarily.

The final rule requires submitters to substantiate claims of confidentiality for chemical identity at the time a notice of commencement of manufacture or import is submitted, and provides that EPA may disclose a chemical identity claimed as confidential but not accompanied by adequate substantiation. As EPA stated in the Interim Policy of May 15, 1979, all information submitted to EPA under the section 5 notice program before the effective date of the final rule will become subject to the confidentiality policies of this rule (45 FR 28567). The Interim Policy does not require submitters to substantiate claims of confidentiality when the notice of commencement is submitted, although EPA encourages them to do so. As a result, EPA has received notices of commencement in which chemical identity was claimed confidential without any accompanying substantiation. Under the final rule, these chemical identities could be disclosed when it goes into effect.

In the May 1979 Interim Policy EPA stated that it would give submitters "ample opportunity to update or modify confidentiality claims prior to becoming subject to any new requirements." EPA believes that 45 days after the effective date of this rule is an ample period for submitters with unsubstantiated claims of confidentiality of chemical identity in notices of commencement of manufacture or import to substantiate those claims. EPA will notify each affected person by letter. If EPA has not received substantiation for the claim within 45 days after the effective date of this rule, it may place the specific chemical identity on the public Inventory consistent with EPA's general procedures for handling confidential information in 40 CFR Part 2.

4. *Health and Safety Studies.* Section 14(a) of TSCA prohibits EPA from disclosing confidential business information reported under the Act except in certain specific circumstances. Section 14(b), however, states that EPA is not prohibited from disclosing health and safety studies of substances for which section 5 notification is required, unless disclosure reveals confidential processes or portions of a mixture. Therefore, EPA cannot refuse to disclose such information in response to an FOIA request, and EPA will deny any claim of confidentiality for the protocol, data, analysis, and results in a health and safety study if the submitter does not establish that disclosure would reveal the following confidential information: (1) process information, (2) portions of a mixture, or (3) information unrelated to the effects of the substance on human health and the environment.

In some submissions, chemical identity may be claimed confidential and attachments to the notice form may contain health and safety studies on the new chemical. EPA will disclose the specific chemical identity that is the subject of those studies if disclosure of chemical identity: (1) is necessary to interpret the health and safety study, and (2) would not reveal confidential process or mixture information. Disclosure of chemical identity is discussed in more detail below.

5. *Specific Chemical Identity.* A major issue in this rulemaking has been the confidentiality of the specific chemical identity that is the subject of a section 5 notice. This issue is of particular concern when health and safety studies are submitted for the substance. Under section 14(b) of TSCA, EPA may not withhold from the public data from health and safety studies unless the data would disclose confidential manufacturing or processing processes or the proportions of specific chemical substances in a mixture. The disclosure requirement applies to data in the study and data underlying the study.

As EPA stated in the January 1979 proposal, the Agency considers the specific chemical identity always to be part of a health and safety study even when it does not appear in the study. Consequently, the chemical identity would be subject to the disclosure requirements of section 14(b). However, in many cases the chemical identity is one of the most commercially sensitive pieces of information in the section 5 notice. Because of the substantial concern expressed by industry about the harm of disclosing confidential chemical identities, EPA explored ways of limiting the commercial harm of such disclosure while still meeting the requirements of section 14(b) of TSCA and providing the public with adequate information about health and safety studies.

In January 1979, EPA proposed that confidential chemical identities would not be released prior to commencement of manufacture or import, even when health and safety studies had been submitted in the notice. After commencement of manufacture, chemical identity would be disclosed if health and safety studies had been submitted and the identity was not exempt under section 14(b) by virtue of revealing a confidential process or confidential proportions of substances in a mixture. Because of the sensitivity of this issue, under its Interim Policy, EPA has honored claims of confidentiality for specific chemical identity, even when health and safety studies have been submitted, reserving a final decision on the issue for this final rule.

This issue generated a great deal of comment. Industry has expressed its concerns about disclosure of confidential chemical identities at any time, while public interest groups and others are concerned that health and safety studies would be meaningless without knowledge of the specific chemical identity involved. In an attempt to meet both these concerns, EPA has chosen an approach that balances the need for confidentiality, the need to understand health and safety studies, and the provisions of TSCA.

Under § 720.85 of the rule, in the absence of any health and safety studies, chemical identity will be held confidential as long as it meets the general tests for confidentiality in 40 CFR Part 2. This is true both before and after commencement of manufacture or import. Under § 720.90(c) of the rule, if any health and safety studies have been submitted for the chemical substance in question, the specific chemical identity will be held confidential only if disclosure would reveal confidential manufacturing or processing processes or the confidential proportions of

substances in a mixture, or if the specific chemical identity is not necessary to interpret any of the studies.

This solution will result in disclosure of a confidential chemical identity only when it is necessary to interpret a health and safety study, unless disclosure would reveal confidential process or mixture information that is protected under section 14(b). This meets concerns expressed by both industry and public interest groups. Industry was concerned that a rule mandating disclosure even when disclosure would not serve any public interest would unnecessarily penalize companies conducting health and safety studies. One the other hand, public interest groups were concerned that disclosure of health and safety studies without the identity of the substance involved would be meaningless if knowledge of the specific identity were necessary to understand the study. Under this approach, companies will be able to present arguments that disclosure of the specific chemical identity is not necessary to interpret a study and, at the same time, members of the public requesting access to studies will be able to argue why disclosure of the specific identity is necessary.

This solution to the issue of confidential chemical identities also has an impact on development of generic chemical names. Companies that claim specific chemical identity confidential in their notices who wish to argue that knowledge of the specific identity is not necessary to interpret their health and safety studies are encouraged to choose generic names which are sufficiently specific to interpret their health and safety studies. Sufficiently specific generic names will tend to support arguments that disclosure of the specific chemical identity is not necessary to understand the study.

IV. Related Rulemaking and Other Actions

A. Section 5(h)(4) Exemptions

Under section 5(h)(4), EPA may, upon application and by rule, exempt manufacturers or importers from all or part of the requirements of section 5 if it determines that the manufacture, import, processing, distribution in commerce, use, or disposal of a new chemical substance will not present an unreasonable risk of injury to health or the environment. Based on its experience in the section 5 review program to date, EPA has promulgated one section 5(h)(4) exemption rule and proposed two others.

EPA promulgated an exemption for new chemicals used in certain instant photographic and peel-apart film articles, published in the **Federal Register** of June 4, 1982 (47 FR 24308). Persons may manufacture these chemicals without undergoing the full 90-day section 5 review, as long as the manufacturer uses certain exposure controls.

EPA also proposed rules to exempt certain site-limited intermediates, low volume chemicals, and polymers, which were published in the **Federal Register** of August 4, 1982 (47 FR 33896). The proposed exemption for site-limited intermediates and chemicals manufactured at 10,000 kg or less per year would exempt these chemicals if they do not have certain adverse health or environmental effects and the manufacturer or importer submits a short notice to EPA 14 days before manufacture begins. A qualified expert would assess the new chemical (unless it was manufactured at 1,000 kg or less per year) to ensure that it met the exemption criteria. The polymer exemption would allow manufacture or import of certain new polymers as long as EPA is notified when manufacture begins. Other new polymers would undergo an abbreviated 14-day section 5 notice review.

EPA is reviewing the comments on these proposed exemptions and intends to issue final exemption rules in mid-1983. If the provisions of the final rules are similar to the provisions in the proposed rules, EPA expects that approximately 60 percent of all new chemicals will qualify for one or more of these exemptions.

B. New Chemical Follow-Up Rules

EPA will promulgate follow-up reporting rules on certain new chemical substances under section 5(a)(2) and 8(a) of TSCA. Such rules will allow EPA to obtain information on selected new chemical substances after they have entered commercial production, and to reassess certain new chemical substances before they are produced for new uses that may significantly increase their risk to human health or the environment.

EPA has proposed significant new use rules (SNURs) and section 8(a) rules for chemical substances in the **Federal Register** and will continue to do so. A SNUR requires persons to notify EPA 90 days before they manufacture, import, or process the substances subject to the rules for a significant new use, as defined by the rule. The same reporting requirements, review procedures, and authorities that apply to notices for new substances apply to SNUR notices. However, if after receipt of a SNUR notice, EPA does not act to regulate the chemical, it must state its reasons in the **Federal Register.** Section 8(a) rules require limited reporting of information; these rules will be used primarily to monitor changes in exposures to chemicals of concern.

Follow-up is an important complement to the section 5 notice review program, which is necessarily limited by the nature of notices on new substances and the section 5 review process. Notices describe the specific uses for which the submitter intends to manufacture or import a new chemical substance and the exposures associated with the intended methods of manufacture, processing, uses, and disposal. EPA will generally base its review and any regulation under section 5(e) or 5(f) on these uses and exposures. In some cases, a substance may raise concern, but the exposure predicted from the information in the notice may not present a significant risk. In these cases, EPA might not take action against the substance during the review period. However, once such a substance has completed section 5 review and has entered commerce, anyone may manufacture, import, or process it for any use without EPA review, even a use likely to result in high levels of exposure that would significantly increase risk. In such a case, EPA might require reporting under a SNUR or section 8(a) rule to ensure review and the opportunity to control these risks before they occur.

C. Testing Guidelines

EPA issued premanufacture testing guidelines which were published in the **Federal Register** of January 27, 1981 (46 FR 8985). In these guidelines, EPA recommends that notice submitters use the Organization for Economic Cooperation and Development (OECD) Minimum Premarket Data set as a starting point in setting up a testing program for new chemicals. EPA is not requiring these data, and a submission that does not contain them would be complete if it otherwise meets the requirements of the Act. Instead, EPA intends that submitters use the testing guidelines flexibly, tailoring their evaluations of new chemicals to the specific new chemicals in question. EPA also encourages submitters to follow any Good Laboratory Practices issued under TSCA.

V. Related Documents

A. Response to Comments

During this rulemaking, EPA has solicited public comment on several proposals and other public documents. These include the January 10, 1979,

proposed rule (44 FR 2242); the October 16, 1979, proposed rule (44 FR 59764); the methodology for the Economic Impact Analysis (44 FR 39450); the proposed processor reporting requirement (45 FR 54642); the clarification of the importer definition (45 FR 63806); the draft Regulatory Analysis and the proposed Economic Impact Analysis (45 FR 74945); and the notice on substantiation of confidentiality claims (47 FR 28969). EPA received numerous comments from individual companies, trade associations, labor unions, public interest organizations, and other groups and individuals. These comments were carefully considered in developing the final rule.

EPA has prepared a detailed Response to Comments on the Premanufacture Notice Requirements and Review Procedures for New Chemical Substances. In this document, EPA has summarized the major comments that it received on the documents listed above and gives its response to each. The Response to Comments is available in the Public Reading Room.

B. Instructions Manual

EPA is also distributing an Instructions Manual for Premanufacture Notification of New Chemical Substances. All persons subject to section 5 notice requirements, or who believe that these requirements may apply to them, should obtain a copy of this manual from the OTS Industry Assistance Office. In the manual, EPA describes: (1) EPA's statutory authority under section 5 of the Act; (2) section 5 reporting requirements; (3) EPA notice review procedures; (4) procedures for asserting and substantiating confidentiality claims; and (5) instructions for completing the notice form.

VI. Regulatory Impact Analysis

Under Executive Order 12291, EPA must determine whether a rule is "major" and therefore subject to the Regulatory Impact Analysis requirement. EPA considers this rule to be major. Although the rule will not have an annual effect on the economy of $100 million or more, the costs of complying with the rule will result in an increase in costs for chemical manufacturers and photographic companies, and there may be some effects on innovation. Also, EPA will incur certain costs to conduct the notice review program. EPA based its classification of this rule as "major" on various studies conducted on the cost of compliance with section 5 notice requirements and the effect of these requirements on new chemical innovation. EPA has prepared a Regulatory Impact Analysis to accompany this rule which summarizes these studies.

EPA included brief regulatory analyses of the January 1979 and October 1979 proposed rules in the preambles to those rules. In November 1980, EPA issued an extensive draft Regulatory Analysis. The Regulatory Impact Analysis that accompanies this rule compares the notice form proposed by EPA in October 1979, a form proposed by the Chemical Manufacturers Association (CMA) in 1979, an in-house draft form comparable to the form required in this rule, and the final form. The Regulatory Impact Analysis concludes that the primary economic effect of the final form is that industry's cost is between $5 million and $12 million annually to complete the notices. These costs are similar to the costs of the CMA form and considerably less than the costs of EPA's October 1979 form.

The Analysis also concludes that while the October 1979 form makes it easier for EPA to identify problem chemicals and take action, the probability of EPA identifying these problem chemical is not significantly lower with the other forms. Thus the incremental benefits of the lengthier October 1979 form are small.

The third major finding of the Regulatory Impact Analysis concerns the distributional effect of the existing notice review program. Based on data from several industry-commissioned surveys and on data in confidential section 5 notice files, it appears that there has been no significant reduction in the number of new chemical innovations since 1979 among the largest companies, but limited data suggest that there probably has been a decline in innovation activity by smaller companies, which tend to produce low volume chemicals. To help reduce this effect on small companies, EPA employs consultants to assist them in preparing notices, at no expense to the submitters.

The fourth major finding of the Analysis is that promulgation of the proposed section 5(h)(4) exemptions to the section 5 notification program would reduce the annual cost to industry of complying with section 5 notification requirements by 19 to 30 percent, to between $4.2 and $9.1 million annually. In addition, the proposed exemptions will significantly reduce the burden of the new chemical review requirements on small firms. If EPA promulgates the provisions in the proposed exemption rules, there will be cost savings of 11 to 35 percent of total notification costs for firms with sales less than $100 million annually.

These findings on cost to submitters were reached by calculating the cost of filing the notice form, the cost of delay (the present value of profits delayed because of the notice review process), the cost of maintaining confidentiality, and the cost of implementing voluntary controls on the manufacturing, processing or marketing of a particular new substance when requested by EPA. The benefit findings were based on EPA's analysis of each case in which it took action on a new chemical substance, to determine what types of information were critical to the decision to seek controls and whether that information would be required on all four forms. If the information would not have been in the submission and if EPA would not have identified the problem through telephone contact or other means, the potential for adverse health effects occasioned by not identifying the problem were determined. The Regulatory Impact Analysis is available for review in the Public Document Room.

This regulation was submitted to the Office of Management and Budget for review as required by Executive Order 12291.

VII. Applicability of Paperwork Reduction Act and Regulatory Flexibility Act

Under the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 *et seq.*, the information provisions in this rule must be submitted for approval to the Office of Management and Budget (OMB). The Agency previously submitted information collection requirements to OMB under the Premanufacture Notification (PMN) Interim Policy which were assigned OMB control number 2000–0054. The information collection requirements in this final rule were approved by OMB and assigned OMB control number 2070–0012.

As required by the Regulatory Flexibility Act (5 U.S.C. 605(b)), EPA has assessed the impact of this rule on small businesses. In various analyses of the chemical industry, small business has been defined in numerous ways, particularly in terms of annual sales levels. To account for different interpretations of the term "small business" within the chemical industry, the Agency analyzed the effect of this rule using two annual sales levels to define small, $30 million and $100 million.

EPA estimates that firms with sales less than $30 million per year will

absorb about 7 percent of total industry-related costs to comply with this rule, or about $0.36 to $0.91 million annually. Firms with sales less than $100 million per year will incur about 13 percent of total industry costs, or about $0.67 to $1.69 million annually. The proposed exemptions will substantially reduce the reporting burden for small companies, however. Taken together, the proposed exemption rules would reduce total program costs for firms with sales less than $30 million and $100 million per year by 11 to 33 percent and 11 to 35 percent, respectively.

VIII. Public Record

EPA has established a public record for this rulemaking (docket number OTS–50002), which is available for inspection in Rm. E–107, 401 M St. SW., Washington, D.C. 20460 from 8:00 a.m. to 4:00 p.m., Monday through Friday, except legal holidays. This record includes all the information considered by EPA in developing this rule except for confidential business information which has been segregated. While part of the record, such information is not available to the public.

The list below describes the information in the record. This list, in accordance with section 19(a)(13) of the Act, identifies the complete rulemaking record:

1. USEPA–OTS. Premanufacture Notification Requirements and Review Procedures. Notice of Proposed Rulemaking.

2. USEPA–OTS. Premanufacture Notification Requirements and Review Procedures: Support Document.

3. USEPA–OTS. Impact of TSCA Premanufacturing Review Requirements (EPA 230/2–12/76–005).

4. Seven working drafts of proposed 40 CFR Part 720 dated from June 20, 1978 to December 3, 1978; three working drafts of the preamble to proposed 40 CFR Part 720 dated from October 28, 1978, to December 3, 1978; eight working drafts of the proposed Premanufacture Notice Form dated from July 30, 1978, to December 3, 1978; two working drafts of the Premanufacture Notice Form for Importers dated from October 5, 1978, to December 3, 1978; three working drafts of the Premanufacture Notice Form for Foreign Manufacturers/Suppliers dated from October 5, 1978, to December 3, 1978; and one draft of the Processing and Consumer Use Form dated December 3, 1978.

5. USEPA–OTS. Reproposal of Premanufacture Notice Forms and Provisions of Rules; Notice of Proposed Rulemaking.

6. USEPA–OTS. Impact of TSCA Proposed Premanufacturing Notification Requirements; contract No. 68–014717.

7. Working drafts of the proposed Premanufacture Notice Forms dated June 28, 1979, July 13, 1979, and August 7, 1979.

8. EPA Documents distributed at the meetings of the Administrator's Toxic Substances Advisory Committee (ATSAC), August 14, 1979, and September 25, 1979.

9. EPA materials on the planned reproposal of the Premanufacture Notice Forms distributed at the Embassy Officials Briefing, September 11, 1979.

10. USEPA–OTS. Premanufacture Notification and Review: Economic Impact.

11. USEPA–OTS. Proposed Processor Reporting Requirements. Notice of Proposed Rulemaking.

12. USEPA–OTS. Cost Estimations of Alternative Processor Notification Requirements; contract no. 68–01–5878.

13. USEPA–OTS. Premanufacture Notification and Review Procedures: Clarification of Importer Reporting Responsibilities.

14. USEPA–OTS. Draft Regulatory Analysis. Premanufacture Notification and Review Procedures.

15. USEPA–OTS. Proposed Economic Impact Analysis of Proposed Section 5 Notice Requirements; contract no. 68–01–5878.

16. USEPA–OTS. Regulatory Impact Analysis of Section 5 Notice Requirements; contract no. 68–01–5878.

17. USEPA–OTS. Response to Comments on New Chemical Notice Requirements & Review Procedures.

18. All factual information and raw data of any sort considered during the rulemaking.

19. EPA correspondence to persons outside EPA concerning this rule.

20 Correspondence (including comments on the proposed rule) received from persons outside EPA before the close of the comment periods, and correspondence received after the close of the comment periods if considered.

21. EPA memoranda summarizing meetings and telephone conversations with outside persons relevant to the development of this rulemaking.

The docket of the record detailing its specific contents is available in the OTS Reading Room.

List of Subjects in 40 CFR Part 720

Chemicals, Environmental protection, Premanufacture notification, Hazardous materials, Recordkeeping and reporting requirements.

Dated: April 26, 1983.

Lee L. Verstandig,

Acting Administrator.

Therefore, 40 CFR Chapter I is amended by adding Part 720 to read as follows:

PART 720—PREMANUFACTURE NOTIFICATION

Subpart A—General Provisions

Subpart B—Applicability

Subpart C—Notice Form

Subpart D—Disposition of Notices

Subpart E—Confidentiality and Public Access to Information

Subpart F—Commencement of Manufacture or Import

Subpart G—Compliance and Inspections

Authority: Toxic Substances Control Act, 15 U.S.C. 2604, 2607, 2613.

Subpart A—General Provisions

§ 720.1 Scope.

This Part establishes procedures for the reporting of new chemical substances by manufacturers and

importers under section 5 of the Toxic Substances Control Act, 15 U.S.C. 2604. The rule defines the persons and chemical substances subject to the reporting requirements, prescribes the contents of section 5 notices, and establishes procedures for submitting notices. The rule also establishes EPA policy regarding claims of confidentiality for, and public disclosure of, various categories of information submitted in connection with section 5 notices (OMB Control No. 2070–0012).

§ 720.3 Definitions.

(a)(1) For the purposes of this Part, the terms "cosmetic," "device," "drug," "food," and "food additive" have the meanings contained in the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 321 *et seq.*, and the regulations issued under it. In addition, the term "food" includes poultry and poultry products, as defined in the Poultry Products Inspection Act, 21 U.S.C. 453 *et seq.*; meats and meat food products, as defined in the Federal Meat Inspection Act, 21 U.S.C. 60 *et seq.*; and eggs and egg products, as defined in the Egg Products Inspection Act, 21 U.S.C. 1033 *et seq.*

(2) The term "pesticide" has the meaning contained in the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. 136 *et seq.* and the regulations issued under it.

(3) The terms "byproduct material," "source material," and "special nuclear material" have the meanings contained in the Atomic Energy Act of 1954, 42 U.S.C 2014 *et seq.* and the regulations issued under it.

(b) "Act" means the Toxic Substances Control Act, 15 U.S.C. 2601 *et seq.*

(c) "Article" means a manufactured item (1) which is formed to a specific shape or design during manufacture, (2) which has end use function(s) dependent in whole or in part upon its shape or design during end use, and (3) which has either no change of chemical composition during its end use or only those changes of composition which have no commercial purpose separate from that of the article and that may occur as described in § 720.36(g)(5), except that fluids and particles are not considered articles regardless of shape or design.

(d) "Byproduct" means a chemical substance produced without a separate commercial intent during the manufacture, processing, use, or disposal of another chemical substance or mixture.

(e) "Chemical substance" means any organic or inorganic substance of a particular molecular identity, including any combination of such substances occurring in whole or in part as a result of a chemical reaction or occurring in nature, and any chemical element or uncombined radical, except that "chemical substance" does not include:

(1) Any mixture.

(2) Any pesticide when manufactured, processed, or distributed in commerce for use as a pesticide.

(3) Tobacco or any tobacco product.

(4) Any source material, special nuclear material, or byproduct material.

(5) Any pistol, firearm, revolver, shells, or cartridges.

(6) Any food, food additive, drug, cosmetic, or device, when manufactured, processed, or distributed in commerce for use as a food, food additive, drug, cosmetic, or device.

(f) "Commerce" means trade, traffic, transportation, or other commerce (1) between a place in a State and any place outside of such State, or (2) which affects trade, traffic, transportation, or commerce between a place in a State and any place outside of such State.

(g) "Customs territory of the United States" means the 50 States, Puerto Rico, and the District of Columbia.

(h) "Director" means the Director of the EPA Office of Toxic Substances.

(i) "Distribute in commerce" means to sell in commerce, to introduce or deliver for introduction into commerce, or to hold after introduction into commerce.

(j) "EPA" means the U.S. Environmental Protection Agency.

(k) "Health and safety study" or "study" means any study of any effect of a chemical substance or mixture on health or the environment or on both, including underlying data and epidemiological studies, studies of occupational exposure to a chemical substance or mixture, toxicological, clinical, and ecological, or other studies of a chemical substance or mixture, and any test performed under the Act. Chemical identity is always part of a health and safety study.

(1) Not only is information which arises as a result of a formal, disciplined study included, but other information relating to the effects of a chemical substance or mixture on health or the environment is also included. Any data that bear on the effects of a chemical substance on health or the environment would be included.

(2) Examples include:

(i) Long- and short-term tests of mutagenicity, carcinogenicity, or teratogenicity; data on behavioral disorders; dermatoxicity; pharmacological effects; mammalian absorption, distribution, metabolism, and excretion; cumulative, additive, and synergistic effects; acute, subchronic, and chronic effects; and structure/activity analyses.

(ii) Tests for ecological or other environmental effects on invertebrates, fish, or other animals, and plants, including: acute toxicity tests, chronic toxicity tests, critical life stage tests, behavioral tests, algal growth tests, seed germination tests, plant growth or damage tests, microbial function tests, bioconcentration or bioaccumulation tests, and model ecosystem (microcosm) studies.

(iii) Assessments of human and environmental exposure, including workplace exposure, and impacts of a particular chemical substance or mixture on the environment, including surveys, tests, and studies of: biological, photochemical, and chemical degradation; air, water, and soil transport; biomagnification and bioconcentration; and chemical and physical properties, e.g., boiling point, vapor pressure, evaporation rates from soil and water, octanol/water partition coefficient, and water solubility.

(iv) Monitoring data, when they have been aggregated and analyzed to measure the exposure of humans or the environment to a chemical substance or mixture.

(v) Any assessments of risk to health and the environment resulting from the manufacture, processing, distribution in commerce, use, or disposal of the chemical substance.

(l) "Importer" means any person who imports a chemical substance, including a chemical substance as part of a mixture or article, into the customs territory of the United States. "Importer" includes the person primarily liable for the payment of any duties on the merchandise or an authorized agent acting on his or her behalf. The term also includes, as appropriate:

(1) The consignee.

(2) The importer of record.

(3) The actual owner if an actual owner's declaration and superseding bond has been filed in accordance with 19 CFR 141.20; or

(4) The transferee, if the right to draw merchandise in a bonded warehouse has been transferred in accordance with Subpart C of 19 CFR 144. (See "principal importer.")

(m) "Impurity" means a chemical substance which is unintentionally present with another chemical substance.

(n) "Intermediate" means any chemical substance that is consumed, in whole or in part, in chemical reactions used for the intentional manufacture of another chemical substance(s) or mixture(s), or that is intentionally present for the purpose of altering the rates of such chemical reactions.

(o) "Inventory" means the list of chemical substances manufactured or processed in the United States that EPA compiled and keeps current under section 8(b) of the Act.

(p) "Known to or reasonably ascertainable by" means all information in a person's possession or control, plus all information that a reasonable person similarly situated might be expected to possess, control, or know.

(q) "Manufacture" means to produce or manufacture in the United States or import into the customs territory of the United States.

(r) "Manufacture or import for commercial purposes" means:

(1) To import, produce, or manufacture with the purpose of obtaining an immediate or eventual commercial advantage for the manufacturer or importer, and includes, among other things, "manufacture" of any amount of a chemical substance or mixture:

(i) For commercial distribution, including for test marketing.

(ii) For use by the manufacturer, including use for product research and development or as an intermediate.

(2) The term also applies to substances that are produced coincidentally during the manufacture, processing, use, or disposal of another substance or mixture, including byproducts that are separated from that other substance or mixture and impurities that remain in that substance or mixture. Byproducts and impurities without separate commercial value are nonetheless produced for the purpose of obtaining a commercial advantage, since they are part of the manufacture of a chemical substance for commercial purposes.

(s) "Manufacture solely for export" means: to manufacture for a commercial purpose solely for export from the United States under the following restrictions on domestic activity:

(1) Processing is limited solely to sites under the control of the manufacturer.

(2) Distribution in commerce is limited to purposes of export.

(3) The manufacturer may not use the substance except in small quantities solely for research and development.

(t) "Manufacturer" means a person who imports, produces, or manufactures a chemical substance. A person who extracts a component chemical substance from a previously existing chemical substance or a complex combination of substances is a manufacturer of that component chemical substance. A person who contracts with a manufacturer to manufacture or produce a chemical substance is also a manufacturer if (1) the manufacturer manufactures or produces the substance exclusively for that person, and (2) that person specifies the identity of the substance and controls the total amount produced and the basic technology for the plant process.

(u) "Mixture" means any combination of two or more chemical substances if the combination does not occur in nature and is not, in whole or in part, the result of a chemical reaction; except "mixture" does include (1) any combination which occurs, in whole or in part, as a result of a chemical reaction if the combination could have been manufactured for commercial purposes without a chemical reaction at the time the chemical substances comprising the combination were combined, and if all of the chemical substances comprising the combination are not new chemical substances, and (2) hydrates of a chemical substance or hydrated ions formed by association of a chemical substance with water, so long as the nonhydrated form is itself not a new chemical substance.

(v) "New chemical substance" means any chemical substance which is not included on the Inventory.

(w) "Nonisolated intermediate" means any intermediate that is not intentionally removed from the equipment in which it is manufactured, including the reaction vessel in which it is manufactured, equipment which is ancillary to the reaction vessel, and any equipment through which the chemical substance passes during a continuous flow process, but not including tanks or other vessels in which the substance is stored after its manufacture.

(x) "Person" means any natural person, firm, company, corporation, joint-venture, partnership, sole proprietorship, association, or any other business entity, any State or political subdivision thereof, any municipality, any interstate body, and any department, agency or instrumentality of the Federal Government.

(y) "Possession or control" means in possession or control of the submitter, or of any subsidiary, partnership in which the submitter is a general partner, parent company, or any company or partnership which the parent company owns or controls, if the subsidiary, parent company, or other company or partnership is associated with the submitter in the research, development, test marketing, or commercial marketing of the chemical substance in question. (A parent company owns or controls another company if the parent owns or controls 50 percent or more of the other company's voting stock. A parent company owns or controls any partnership in which it is a general partner.) Information is included within this definition if it is:

(1) In the submitter's own files including files maintained by employees in the course of their employment.

(2) In commercially available data bases to which the submitter has purchased access.

(3) Maintained in the files in the course of employment by other agents of the submitter who are associated with research, development, test marketing, or commercial marketing of the chemical substance in question.

(z) "Principal importer" means the first importer who, knowing that a new chemical substance will be imported rather than manufactured domestically, specifies the identity of the chemical substance and the total amount to be imported. Only persons who are incorporated, licensed, or doing business in the United States may be principal importers.

(aa) "Process" means the preparation of a chemical substance or mixture, after its manufacture, for distribution in commerce (1) in the same form or physical state as, or in a different form or physical state from, that in which it was received by the person so preparing such substance or mixture, or (2) as part of a mixture or article containing the chemical substance or mixture.

(bb) "Processor" means any person who processes a chemical substance or mixture.

(cc) "Small quantities solely for research and development" (or "small quantities solely for purposes of scientific experimentation or analysis or chemical research on, or analysis of, such substance or another substance, including such research or analysis for the development of a product") means quantities of a chemical substance manufactured, imported, or processed or proposed to be manufactured, imported, or processed solely for research and development that are not greater than reasonably necessary for such purposes.

(dd) "State" means any State of the United States and the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, the Canal Zone, American Samoa, the Northern Mariana Islands, and any other territory or possession of the United States.

(ee) "Technically qualified individual" means a person or persons (1) who, because of education, training, or experience, or a combination of these factors, is capable of understanding the health and environmental risks associated with the chemical substance which is used under his or her supervision, (2) who is responsible for

enforcing appropriate methods of conducting scientific experimentation, analysis, or chemical research to minimize such risks, and (3) who is responsible for the safety assessments and clearances related to the procurement, storage, use, and disposal of the chemical substance as may be appropriate or required within the scope of conducting a research and development activity.

(ff) "Test data" means data from a formal or informal test or experiment, including information concerning the objectives, experimental methods and materials, protocols, results, data analyses, recorded observations, monitoring data, measurements, and conclusions from a test or experiment.

(gg) "Test marketing" means the distribution in commerce of no more than a predetermined amount of a chemical substance, mixture, or article containing that chemical substance or mixture, by a manufacturer or processor, to no more than a defined number of potential customers to explore market capability in a competitive situation during a predetermined testing period prior to the broader distribution of that chemical substance, mixture, or article in commerce.

(hh) "United States," when used in the geographic sense, means all of the States.

Subpart B—Applicability

§ 720.22 Persons who must report.

(a) (1) Any person who intends to manufacture a new chemical substance in the United States for commercial purposes must submit a notice unless the substance is excluded under § 720.30.

(2) If a person contracts with a manufacturer to manufacture or produce a new chemical substance, and (i) the manufacturer manufactures or produces the substance exclusively for that person, and (ii) that person specifies the identity of the substance, and controls the total amount produced and the basic technology for the plant process, that person must submit the notice. If it is unclear who must report, EPA should be contacted to determine who must submit the notice.

(3) Only manufacturers that are incorporated, licensed, or doing business in the United States may submit a notice.

(b)(1) Any person who intends to import a new chemical substance into the United States for commercial purposes must submit a notice, unless the substance is excluded under § 720.30 or unless the substance is imported as part of an article.

(2) When several persons are involved in an import transaction, the notice must be submitted by the principal importer. If no one person fits the principal importer definition in a particular transaction, the importer should contact EPA to determine who must submit the notice for that transaction.

§ 720.25 Determining whether a chemical substance is on the Inventory.

(a) A new chemical substance is a chemical that is not on the Inventory.

(b)(1) A chemical substance is listed on the Inventory by specific chemical name if its identity is not confidential. If its identity is confidential, it is listed by specific name in the confidential portion of the Inventory. The confidential chemical substance is also listed on the public Inventory by a generic name which masks the specific identity. A person who intends to manufacture or import a chemical substance not listed on the Inventory by specific chemical name may ask EPA whether the substance is included on the confidential Inventory. EPA will answer such an inquiry only if EPA determines that the person has a *bona fide* intent to manufacture or import the chemical substance for commercial purposes.

(2) To establish a *bona fide* intent to manufacture or import a chemical substance, the person who proposes to manufacture or import the substance must submit to EPA:

(i) The specific chemical identity of the substance that the person intends to manufacture or import.

(ii) A signed statement that the person intends to manufacture or import that chemical substance for commercial purposes.

(iii) A description of the research and development activities conducted to date, and the purpose for which the person will manufacture or import the chemical substance.

(iv) An elemental analysis.

(v) Either an X-ray diffraction pattern (for inorganic substances), a mass spectrum (for most other substances), or an infrared spectrum of the particular chemical substance, or if such data do not resolve uncertainties with respect to the identity of the chemical substance, additional or alternative spectra or other data to identify the substance.

(3) If an importer cannot provide all the information required by paragraph (b)(2) of this section because it is claimed confidential business information by its foreign manufacturer or supplier, the foreign manufacturer or supplier may supply the information directly to EPA.

(4) EPA will review the information submitted by the proposed manufacturer or importer under this paragraph to determine whether it has a *bona fide* intent to manufacture or import the chemical substance. If necessary, EPA will compare this information either to the information requested for the confidential chemical substance under § 710.7(e)(2)(v) of this Chapter or the information requested under § 720.85(b)(3)(iii).

(5) If the proposed manufacturer or importer has shown a *bona fide* intent to manufacture or import the substance, and provide sufficient unambiguous chemical identity information so EPA can make a conclusive determination of the chemical substance's Inventory status, EPA will search the confidential Inventory and inform the proposed manufacturer or importer whether the chemical substance is on the confidential Inventory.

(6) If the chemical substance is found on the confidential Inventory, EPA will notify the person(s) who originally reported the chemical substance that another person has demonstrated a *bona fide* intent to manufacture or import the substance and therefore was told that the chemical substance is on the Inventory.

(7) A disclosure of a confidential chemical identity to a person with a *bona fide* intent to manufacture or import the particular chemical substance will not be considered a public disclosure of confidential business information under section 14 of the Act.

(8) EPA will answer an inquiry on whether a particular chemical substance is on the confidential Inventory within 30 days after receipt of a complete submission under paragraph (b)(2) of this section (OMB Control No. 2070–0012).

§ 720.30 Chemicals not subject to notification requirements.

The following substances are not subject to the notification requirements of this Part:

(a) Any substance which is not a "chemical substance" as defined in § 720.3(e).

(b) Any mixture as defined in § 720.3(u).[1]

(c) Any new chemical substance which will be manufactured or imported in small quantities solely for research and development under § 720.36.

(d) Any new chemical substance which will be manufactured or imported

[1] A new chemical substance that is manufactured or imported as part of a mixture is subject to the requirements of this Part. This exclusion applies only to a mixture as a whole and not to any chemical substances which are part of the mixture.

solely for test-marketing purposes under an exemption granted under § 720.38.

(e) Any new chemical substance manufactured solely for export.

(f) Any new chemical substance which is manufactured or imported under the terms of a rule promulgated under section 5(h)(4) of the Act.

(g) Any byproduct if its only commercial purpose is for use by public or private organizations that (1) burn it as a fuel, (2) dispose of it as a waste, including in a landfill or for enriching soil, or (3) extract component chemical substances from it for commercial purposes. (This exclusion only applies to the byproduct; it does not apply to the component substances extracted from the byproduct.)

(h) The chemical substances described below: (Although they are manufactured for commercial purposes under the Act, they are not manufactured for distribution in commerce as chemical substances per se and have no commercial purpose separate from the substance, mixture, or article of which they are a part.)

(1) Any impurity.

(2) Any byproduct which is not used for commercial purposes.

(3) Any chemical substance which results from a chemical reaction that occurs incidental to exposure of another chemical substance, mixture, or article to environmental factors such as air, moisture, microbial organisms, or sunlight.

(4) Any chemical substance which results from a chemical reaction that occurs incidental to storage or disposal of another chemical substance, mixture, or article.

(5) Any chemical substance which results from a chemical reaction that occurs upon end use of another chemical substance, mixture, or article such as an adhesive, paint, miscellaneous cleanser or other housekeeping product, fuel additive, water softening and treatment agent, photographic film, battery, match, or safety flare, and which is not itself manufactured or imported for distribution in commerce or for use as an intermediate.

(6) Any chemical substance which results from a chemical reaction that occurs upon use of curable plastic or rubber molding compounds, inks, drying oils, metal finishing compounds, adhesives, or paints, or any other chemical substance formed during the manufacture of an article destined for the marketplace without further chemical change of the chemical substance except for those chemical changes that occur as described elsewhere in this paragraph.

(7) Any chemical substance which results from a chemical reaction that occurs when (i) a stabilizer, colorant, odorant, antioxidant, filler, solvent, carrier, surfactant, plasticizer, corrosion inhibitor, antifoamer or defoamer, dispersant, precipitation inhibitor, binder, emulsifier, deemulsifier, dewatering agent, agglomerating agent, adhesion promoter, flow modifier, pH neutralizer, sequesterant, coagulant, flocculant, fire retardant, lubricant, chelating agent, or quality control reagent functions as intented, or (ii) a chemical substance, which is intended solely to impart a specific physiochemical characteristic, functions as intended.

(8) Any nonisolated intermediate.

§ 720.36 Exemptions for research and development.

(a) This Part does not apply to a chemical substance if:

(1) The chemical substance is manufactured or imported only in small quantities solely for research and development.

(2) The manufacturer or importer (i) evaluates the chemical substance in accordance with paragraph (b) of this section, and (ii) notifies all persons engaged in experimentation, research, or analysis on the new chemical substance, including the manufacture, processing, use, transport, storage, and disposal of the substance associated with research and development activities, of any risk to health, identified under paragraph (b) of this section, which may be associated with the substance, in accordance with paragraph (c) of this section. A technically qualified individual must ensure the adequacy of the notification.

(3) The chemical substance is used by, or directly under the supervision of, a technically qualified individual.

(b)(1) The manufacturer or importer must evaluate any information or test data in its possession or control to determine whether there is reason to believe there is any risk to health associated with the chemical substance. This information must include:

(i) Any information concerning any significant adverse reaction by persons exposed to the substance which may reasonably be associated with such exposure.

(ii) Any information provided to the manufacturer or importer by a supplier or any other person concerning a health risk believed to be associated with the substance.

(2) In addition, the manufacturer or importer must determine whether the substance is subject to any rule or order proposed or promulgated under section 4, 5, or 6 of the Act; or the notice requirements of section 8(e) of the Act. In addition, the manufacturer or importer must ascertain whether EPA, under section 5(h)(3) of the Act, has determined that any risk to health may be associated with the substance.

(c) The manufacturer or importer must assure that persons are notified by means of a container labeling system, conspicuous placement of notices in areas where exposure may occur, written notification to each person, or any other method of notification which adequately informs persons of risks which the manufacturer or importer has reason to believe may be associated with the substance, as determined under paragraph (b) of this section. The adequacy of the notification is the responsibility of the manufacturer or importer. If the importer is not the manufacturer, it is the importer's responsibility to make the necessary evaluation and notification of any risks to health which may be associated with the substance. In making such evaluations, the importer must obtain that information described in paragraph (b) of this section which is reasonably ascertainable.

(d) Upon request, the manufacturer or importer must make available to EPA any information evaluated by the manufacturer or importer in determining the need for notification under paragraph (a)(2)(ii) of this section.

(e) The requirements for this exemption apply to all new chemical substances, including chemical substances manufactured or imported under such an exemption before the effective date of this rule.

§ 720.38 Exemptions for test marketing.

(a) Any person may apply for an exemption to manufacture or import a new chemical substance for test marketing. EPA may grant the exemption if the person demonstrates that the chemical substance will not present an unreasonable risk to injury to health or the environment as a result of the test marketing.

(b) Persons applying for a test-marketing exemption should provide the following information:

(1) All existing data regarding health and environmental effects of the chemical substance, including physical/chemical properties or, in the absence of such data, a discussion of toxicity based on structure-activity relationships (SAR) and relevant data on chemical analogues.

(2) The maximum quantity of the chemical substance which the applicant will manufacture or import for test marketing.

(3) The maximum number of persons who may be provided the chemical substance during test marketing.

(4) The maximum number of persons who may be exposed to the chemical substance as a result of test marketing, including information regarding duration and route of such exposures.

(5) A description of the test-marketing activity, including its length and how it can be distinguished from full-scale commercial production and research and development.

(c) In accordance with section 5(h)(6) of the Act, after EPA receives an application for exemption under this section, the Agency will file with the Office of the Federal Register a notice containing a summary of the information provided in the application, to the extent it has not been claimed confidential.

(d) No later than 45 days after EPA receives an application, the Agency will either approve or deny the application. Thereafter, EPA will publish a notice in the **Federal Register** explaining the reasons for approval or denial.

(e) In approving an application for exemption, EPA may impose any restrictions necessary to ensure that the substance will not present an unreasonable risk of injury to health and the environment as a result of test marketing (OMB Control No. 2070–0012).

Subpart C—Notice Form

§ 720.40 General.

(a) *Use of the notice form.* Each person who is required by Subpart B to submit a notice must complete, sign, and submit a notice containing the information in the form and manner set forth in EPA Form No. 7710–25 [2] under Appendix A of this part. Except as otherwise provided in Subpart C, each notice must be submitted with all referenced attachments. The information on the form and all attachments (unless the attachment appears in the open scientific literature) must be in English. All information submitted must be true and correct.

(b) *When to submit a notice.* Each person who is required to submit a notice must submit the notice at least 90 calendar days before manufacture or import of the new chemical substance for commercial purposes begins.

(c) *Where to submit a notice.* Each person who submits a notice must submit it to the address listed on the notice form.

(d) *General notice requirements.* Each person who submits a notice must provide the information described in § 720.45 and specified on the notice form, to the extent such information is known to or reasonably ascertainable by the submitter. In accordance with § 720.50, the notice must also include any test data in the submitter's possession or control and descriptions of other data which are known to or reasonably ascertainable by the submitter and which concern the health and environmental effects of the new chemical substance.

(e) *Agency or joint submissions.* (1) A manufacturer or importer may designate an agent to submit the notice. Both the manufacturer or importer and the agent must sign the certification on the form.

(2) A manufacturer or importer may authorize another person, (e.g., a foreign manufacturer or supplier, or a toll manufacturer) to report some of the information required in the notice to EPA on its behalf. If separate portions of a joint notice are not submitted together, the submitter should indicate which information will be supplied by another person and identify that person. The other person must submit the information on the appropriate part of the notice form. The manufacturer or importer and any other person supplying the information must sign the certification provided on their respective notice forms.

(3) If EPA receives a submission which does not include information required by this rule, which the submitter indicates that it has authorized another person to provide, the notice review period will not begin until EPA receives that information.

(f) *New information.* During the notice review period, if the submitter possesses, controls, or knows of new information that materially adds to, changes, or otherwise makes significantly more complete the information included in the notice, the submitter must that information to the address listed on the notice form within ten days of receiving the new information, but no later than five days before the end of the notice review period. The new submission must clearly identify the submitter and the notice to which the new information is related. If the new information becomes available during the last five days of the notice review period, the submitter must immediately inform its EPA contract for that notice by telephone.

(g) *Chemical substances subject to a section 4 test rule.*

(1) Except as provided in paragraph (g)(3) of this section, if (i) A person intends to manufacture or import a new chemical substance which is subject to the notification requirements of this Part, and (ii) The chemical substance is subject to a test rule promulgated under section 4 of the Act before the notice is submitted, section 5(b)(1) of the Act requires the person to submit the test data required by the testing rule with the notice. The person must submit the data in the form and manner specified in the test rule and in accordance with § 720.50. If the person does not submit the test data, the submission is incomplete and EPA will follow the procedures in § 720.65.

(2) If EPA has granted the submitter an exemption under section 4(c) of the Act from the requirement to conduct tests and submit data, the submitter may not submit a notice until EPA receives the test data.

(3) If EPA has granted the submitter an exemption under section 4(c) of the Act and if another person previously has submitted the test data to EPA, the exempted person may either submit the test data or provide the following information as part of the notice:

(i) The name, title, and address of the person who submitted the test data to EPA.

(ii) The date the test data were submitted to EPA.

(iii) A citation for the test rule.

(iv) A description of the exemption and a reference identifying it.

(h) *Chemical substances subject to a section 5(b)(4) rule.* (1) If a person (i) intends to manufacture or import a new chemical substance which is subject to the notification requirements of this part and which is subject to a rule issued under section 5 (b)(4) of the Act; and (ii) is not required by a rule issued under section 4 of the Act to submit test data for the substance before the submission of a notice, the person must submit to EPA data described in paragraph (h)(2) of this section at the time the notice is submitted.

(2) Data submitted under paragraph (h)(1) of this section must be data which the person submitting the notice believes show that the manufacture, processing, distribution in commerce, use and disposal of the substance, or any combination of such activities, will not present an unreasonable risk of injury to health or the environment (OMB Control No. 2070–0012).

§ 720.45 Information that must be included in the notice form.

Each person who submits a notice must include the information specified in the notice form to the extent it is known to or reasonably ascertainable by the submitter. However, no person is required to include information which relates solely to exposure of human or

[2] Copies may be obtained from: Industry Assistance Office (TS–799), Office of Toxic Substances, Environmental Protection Agency, 401 M St., SW. Washington, D.C. 20460.

ecological populations outside of the United States. The notice form requires the following information relating to the manufacture, processing, distribution in commerce, use, and disposal of the new chemical substance:

(a)(1) For substances whose composition can be represented by a definite structural diagram (class 1 substances), the notice must provide the chemical name (preferably Chemical Abstracts Service (CAS) or International Union of Pure and Applied Chemistry (IUPAC) nomenclature), the molecular formula, CAS Registry Number (if available), and a structural diagram.

(2) For chemical substances that cannot be fully represented by a structural diagram (class 2 substances), the notice must provide the chemical name, the CAS Registry Number (if available), and molecular formula. The notice must identify the immediate precursors and reactants by name and CAS Registry Number (if the number is available). The notice must include a partial or incomplete structural diagram if possible. Chemical names for such substances should be developed according to the guidelines in the TSCA Chemical Substance Inventory, Initial Inventory, Volume 1.

(3) For polymers, the notice must identify monomers and other reactants used in the manufacture of the polymer by chemical name and CAS Registry Number (if available). The notice must indicate the typical percent of each monomer and other reactant in the polymer (by weight percent of total polymer); the maximum residual of each monomer present in the polymer; and a partial or incomplete structural diagram, if possible. The notice must provide estimates of the minimum number-average molecular weight of the polymer and the amount of low weight species below 500 and below 1,000 molecular weight and describe how the estimates were obtained.

(b) The impurities anticipated to be present in the substance by name, CAS Registry number, and weight percent of the total substance.

(c) Known synonyms or trade names of the new chemical substance.

(d) A description of the byproducts resulting from the manufacture, processing, use, and disposal of the new chemical substance.

(e) The estimated maximum amount to be manufactured or imported during the first year of production and the estimated maximum amount to be manufactured or imported during any 12-month period during the first three years of production.

(f) A description of intended categories of use by function and application, the estimated percent of production volume devoted to each category of use, and the percent of the new substance in the formulation for each commercial or consumer use.

(g) For sites controlled by the submitter:

(1) The identity of sites where the new substance will be manufactured, processed, or used.

(2) A process description of each manufacture, processing, and use operation which includes a diagram of the major unit operations and chemical conversions, the identity and entry point of all feedstocks, and the points of release of the new chemical substance.

(3) Worker exposure information, including worker activities, physical form of the new substance to which workers may be exposed, the number of workers, and the duration of activities.

(4) Information on release of the new substance to the environment, including the quantity and media of release and type of control technology used.

(h) For sites not controlled by the submitter, a description of each type of processing and use operation involving the new chemical substance, including identification of the estimated number of processing or use sites, situations in which worker exposure to and/or environmental release of the new chemical substance will occur, the number of workers exposed and the duration of exposure, and controls which limit worker exposure and environmental release.

§ 720.50 Submission of test data and other data concerning the health and environmental effects of a substance.

(a) *Test data on the new chemical substance in the possession or control of the submitter.* (1) Except as provided in paragraph (d) of this section, each notice must contain all test data in the submitter's possession or control which are related to the effects on health or the environment of any manufacture, processing, distribution in commerce, use, or disposal of the new chemical substance or any mixture or article containing the new chemical substance, or any combination of such activities. This includes test data concerning the new chemical substance in a pure, technical grade, or formulated form.

(2) A full report or standard literature citation must be submitted for the following types of test data:

(i) Health effects data.

(ii) Ecological effects data.

(iii) Physical and chemical properties data.

(iv) Environmental fate characteristics.

(v) Monitoring data and other test data related to human exposure to or environmental release of the chemical substance.

(3)(i) If the data do no appear in the open scientific literature, the submitter must provide a full report. A full report includes the experimental methods and materials, results, discussion and data analysis, conclusions, references, and the name and address of the laboratory that developed the data.

(ii) If the data appear in the open scientific literature, the submitter need only provide a standard literature citation. A standard literature citation includes author, title, periodical name, date of publication, volume, and page numbers.

(4) (i) If a study, report, or test is incomplete when a person submits a notice, the submitter must identify the nature and purpose of the study; name and address of the laboratory developing the data; progress to date; types of data collected; significant preliminary results; and anticipated completion date.

(ii) If a test or experiment is completed before the notice review period ends, the person must submit the study, report, or test to the address listed on the notice form, as specified in paragraph (a)(3)(i) of this section, within ten days of receiving it, but no later than five days before the end of the review period. If the test or experiment is completed during the last five days of the review period, the submitter must immediately inform its EPA contact for that notice by telephone.

(5) For test data in the submitter's possession or control which are not listed in paragraph (a)(2) of this section, a person is not required to submit a complete report. The person must submit a summary of the data. If EPA so requests, the person must submit a full report within ten days of the request, but no later than five days before the end of the review period.

(6) All test data described by paragraph (a) are subject to these requirements, regardless of their age, quality, or results.

(b) *Other data concerning the health and environmental effects of the new chemical substance that are known to or reasonably ascertainable by the submitter.* (1) Except as provided in paragraph (d) of this section, any person who submits a notice must describe the following data, including any data from a health and safety study, if the data are related to the effects on health or the environment of any manufacture, processing, distribution in commerce, use, or disposal of the new chemical

substance, of any mixture or article containing the new chemical substance, or of any combination of such activities:

(i) Any data, other than test data, in the submitter's possession or control.

(ii) Any data, including test data, which are not in the submitter's possession or control, but which are known to or reasonably ascertainable by the submitter. For the purposes of this section, data are known to or reasonably ascertainable by the submitter if the data are known to any of its employees or other agents who are associated with the research and development, test marketing, or commercial marketing of the substance.

(2) Data that must be described include data concerning the new chemical substance in a pure, technical grade, or formulated form.

(3) The description of data reported under this paragraph must include:

(i) If the data appear in the open scientific literature, a standard literature citation, which includes the author, title, periodical name, date of publication, volume, and pages.

(ii) If the data are not contained in the open scientific literature, a description of the type of data and summary of the results, if available, and the names and addresses of persons the submitter believes may have possession or control of the data.

(4) All data described by this paragraph are subject to these requirements, regardless of their age, quality, or results; and regardless of whether they are complete at the time the notice is submitted.

(c) *Data concerning related chemicals.* A person must submit test data or descriptions of other data concerning impurities, byproducts, degradation products, unintended reaction products, or other chemical substances or mixtures related to the manufacture, processing, distribution in commerce, use, or disposal of the new chemical substance only if the data have not been published in the open scientific literature. The submitter may either submit these data with the notice or describe them in accordance with § 720.50(b)(3)(ii), rather than providing a full report.

(d) *Data that need not be submitted—*(1) *Data previously submitted to EPA.* (i) A person need not submit any data previously submitted to EPA with no claims of confidentiality if the notice includes the office or person to whom the data were submitted, the date of submission, and, if appropriate, a standard literature citation as specified in paragraph (a)(3)(ii) of this section.

(ii) For data previously submitted to EPA with a claim of confidentiality, the person must resubmit the data with the notice and any claim of confidentiality, under § 720.80.

(2) *Efficacy data.* This Part does not require submission of any data related solely to product efficacy. This does not exempt a person from submitting any of the data specified in paragraph (a), (b), or (c) of this section.

(3) *Non-U.S. exposure data.* This Part does not require submission of any data which relates only to exposure of humans or the environment outside the United States. This does not exclude nonexposure data such as data on health effects (including epidemiological studies), ecological effects, physical and chemical properties, or environmental fate characteristics.

§ 720.57 Imports.

(a) Except as otherwise provided in this section, the provisions of this Subpart C apply to each person who submits a notice for a new chemcial substance which he or she intends to import for a commercial purpose. In addition, each importer must comply with this section.

(b) EPA will hold the principal importer, or the importer that EPA determines must submit the notice when there is no principal importer under § 720.22(b) (2), liable for complying with this Part, for completing the notice form and for the completeness and truthfulness of all information which it submits.

Subpart D—Disposition of Notices

§ 720.60 General.

This subpart establishes procedures that EPA will follow in reviewing notices.

§ 720.62 Notice that notification is not required.

When EPA receives a notice, EPA will review it to determine whether the chemical substance is subject to the requirements of this Part. If EPA determines that the chemical substance is not subject to these requirements, EPA will notify the submitter that section 5 of the Act does not prevent the manufacture or import of the substance and that the submission is not a notice under this Part (OMB Control No. 2070–0012).

§ 720.65 Acknowledgment of receipt of a notice; errors in the notice; incomplete submissions; false and misleading statements.

(a) *Notification to submitter.* EPA will acknowledge receipt of each notice by sending the submitter a letter that identifies the premanufacture notice number assigned to the new chemical substance and the date on which the review period begins. The review period will begin on the date the notice is received by the Office of Toxic Substances Document Control Officer. The acknowledgment does not constitute a finding by EPA that the notice, as submitted, is in compliance with this Part.

(b) *Errors in the notice.* (1) Within 30 days of receipt of the notice, EPA may request that the submitter remedy errors in the notice. The following are examples of such errors:

(i) Failure to date the notice form.

(ii) Typographical errors that cause data to be misleading or answers to any questions to be unclear.

(iii) Contradictory information.

(iv) Ambiguous statements or information.

(2) In the request to correct the notice, EPA will explain the action which the submitter must take to correct the notice.

(3) If the submitter fails to correct the notice within 15 days of receipt of the request EPA may extend the notice period under section (5)(c) of the Act, in accordance with § 720.75(c).

(c) *Incomplete submissions.* (1) A submission is not complete, and the notification period does not begin, if:

(i) The wrong person submits the notice form.

(ii) The submitter does not sign the notice form.

(iii) Some or all of the information in the notice or the attachments are not in English, except for published scientific literature.

(iv) The submitter does not use the notice form.

(v) The submitter does not provide information that is required by section 5(d)(1) (B) and (C) of the Act and § 720.50.

(vi) The submitter does not provide information required on the notice form and by § 720.45 or indicate that it is not known to or reasonably ascertainable by the submitter.

(vii) The submitter does not submit a second copy of the submission with all confidential information deleted for the public file, as required by § 720.80(b)(2).

(viii) The submitter does not include any information required by section 5(b)(1) of the Act and pursuant to a rule promulgated under section 4 of the Act, as required by § 720.40(g).

(ix) The submitter does not submit data which the submitter believes show that the chemical substance will not present an unreasonable risk of injury to health or the environment, if EPA has listed the chemical substance under

section 5(b)(4) of the Act, as required in § 720.40(h).

(2)(i) If EPA receives an incomplete submission, the Director, or his or her delegate, will notify the submitter within 30 days of receipt that the submission is incomplete and that the notice review period will not begin until EPA receives a complete notice.

(ii) If EPA obtains additional information during the notice review period that indicates the original submission was incomplete, the Director, or his or her delegate, may declare the submission incomplete within 30 days after EPA obtains the additional information and so notify the submitter.

(3) The notification that a submission is incomplete under paragraph (c)(2) (i) or (ii) of this section will include:

(i) A statement of the basis of EPA's determination that the submission is incomplete.

(ii) The requirements for correcting the incomplete submission.

(iii) Information on procedures under paragraph (c)(4) of this section for filing objections to the determination or requesting modification of the requirements for completing the submission.

(4) Within ten days after receipt of notification by EPA that a submission is incomplete, the submitter may file written objections requesting that EPA accept the submission as a complete notice or modify the requirements necessary to complete the submission.

(5)(i) EPA will consider the objections filed by the submitter. The Director, or his or her delegate, will determine whether the submission was complete or incomplete, or whether to modify the requirements for completing the submission. EPA will notify the submitter in writing of EPA's response within ten days of receiving the objections.

(ii) If the Director, or his or her delegate, determines, in response to the objection, that the submission was complete, the notice review period will be deemed suspended on the date EPA declared the notice incomplete, and will resume on the date that the notice is declared complete. The submitter need not correct the notice as EPA originally requested. If EPA can complete its review within 90 days from the date of the original submission, the Director, or his or her delegate, may inform the submitter that the running of the review period will resume on the date EPA originally declared it incomplete.

(iii) If the Director, or his or her delegate, modifies the requirements for completing the submission or concurs with EPA's original determination, the notice review period will begin when EPA receives a complete notice.

(d) *Materially false or misleading statements.* If EPA discovers at any time that person submitted materially false or misleading statements in the notice, EPA may find that the notice was incomplete from the date it was submitted, and take any other appropriate action.

§ 720.70 Notice in the Federal Register.

(a) *Filing of* **Federal Register** *notice.* In accordance with section 5(d)(2) of the Act, after EPA receives a notice, EPA will file with the Office of the Federal Register a notice including the information specified in paragraph (b) of this section.

(b) *Contents of notice.* (1) In the public interest, the specific chemical identity listed in the notice will be published in the **Federal Register** unless the submitter has claimed chemical identity confidential. If the submitter claims confidentiality, a generic name will be published in accordance with § 720.85(a)(3).

(2) The categories of use of the new chemical substance will be published as reported in the notice unless this information is claimed confidential. If confidentiality is claimed, the generic information which is submitted under § 720.87(b) will be published.

(3) A list of data submitted in accordance with § 720.50(a) will be published. In addition, for test data submitted in accordance with § 720.40(g), a summary of the data will be published.

(4) The submitter's identity will be published, unless the submitter has claimed it confidential.

§ 720.75 Notice review period.

(a) *Length of notice review period.* The notice review period specified in section 5(a) of the Act runs for 90 days from the date the Document Control Officer for the Office of Toxic Substances receives a complete notice, or the date EPA determines the notice is complete under § 720.65(c), unless the Agency extends the period under section 5(c) of TSCA and paragraph (c) of this section.

(b) *Suspension of the running of the notice review period.* (1) A submitter may voluntarily suspend the running of the notice review period if the Director or his or her delegate agrees. If the Director does not agree, the review period will continue to run, and EPA will notify the submitter. A submitter may request a suspension at any time during the notice review period. The suspension must be for a specified period of time.

(2) A request for suspension may be made in writing to the Document Control Officer (TS–793), Office of Pesticides and Toxic Substances, 401 M Street SW., Washington, D.C. 20460. The suspension also may be made orally, including by telephone, to the submitter's EPA contact for that notice. EPA will send the submitter a written confirmation that the suspension has been granted (OMB Control No. 2070–0012).

(i) An oral request may be granted for 15 days only. To obtain a longer suspension, the Document Control Officer for the Office of Toxic Substances must receive written confirmation of the oral request. The notice review period is suspended as of the date of the oral request.

(ii) If the submitter has not made a previous oral request, the running of the notice review period is suspended as of the date of receipt of the written request by the Document Control Officer for the Office of Toxic Substances.

(c) *Extension of notice review period.* (1) At any time during the notice review period, EPA may determine that good cause exists to extend the notice review period specified in paragraph (a) of this section.

(2) If EPA makes such a determination, EPA will:

(i) Notify the submitter that EPA is extending the notice review period for a specified length of time, and state the reasons for the extension.

(ii) Issue a notice for publication in the **Federal Register** which states that EPA is extending the notice review period and gives the reasons for the extension.

(3) The initial extension may be for a period of up to 90 days. If the initial extension is for less than 90 days, EPA may make additional extensions. However, the total period of extensions may not exceed 90 days for any notice.

(4) The following are examples of situations in which EPA may find that good cause exists for extending the notice review period:

(i) EPA has reviewed the notice and determined that there is a significant possibility that the chemical substance will be regulated under section 5(e) or section 5(f) of the Act, but EPA is unable to initiate regulatory action within the initial 90-day period.

(ii) EPA has reviewed the submission and is seeking additional information.

(iii) EPA has received significant additional information during the notice review period.

(iv) The submitter has failed to correct a notice after receiving EPA's request under § 720.65(b).

(d) *Notice of expiration of notice review period.* EPA will notify the submitter that the notice review period has expired or that EPA has completed its review of the notice. Expiration of the review period does not constitute EPA approval or certification of the new chemical substance, and does not mean that EPA may not take regulatory action against the substance in the future. After expiration of the statutory notice review period, in the absence of regulatory action by EPA under section 5(e), 5(f), or 6(a) of the Act, the submitter may manufacture or import the chemical substance even if the submitter has not received notice of expiration.

(e) *Withdrawal of a notice by the submitter.* (1) A submitter may withdraw a notice during the notice review period. A statement of withdrawal must be made in writing to the Document Control Officer (TS–793), Office of Pesticides and Toxic Substances, 401 M St. SW., Washington, D.C. 20460. The withdrawal is effective upon receipt of the statement by the Document Control Officer (OMB Control No. 2070–0012).

(2) If a manufacturer or importer which withdrew a notice later resubmits a notice for the same chemical substance, a new notice review period begins.

§ 270.78 Recordkeeping

(a) Any person who submits a notice under this Part must retain documentation of information in the notice, including (1) other data, as defined in § 720.50(b), in the submitter's possession or control; and (2) records of production volume for the first three years of production or import, the date of commencement of manufacture or import, and documentation of this information. This information must be retained for five years from the date of commencement of manufacture of import.

(b) Persons who manufacture or import a chemical substance under the terms of a research and development exemption must retain documentation of compliance with the exemption, including copies of the information they used to determine the need to make any notification of risk to health under § 720.36 for five years from the final date of manufacture or import under the exemption.

(c) Any person who obtains a test-marketing exemption under this Part must retain documentation of information in the application and documentation of compliance with any restrictions imposed by EPA when it granted the application. This information must be retained for five years from the final date of manufacture or import under the exemption (OMB Control No. 2070–0012).

Subpart E—Confidentiality and Public Access to Information

§ 720.80 General provisions.

(a) A person may assert a claim of confidentiality for any information which he or she submits to EPA under this Part.

(b) Any claim of confidentiality must accompany the information when it is submitted to EPA.

(1)(i) For information submitted on the notice form, the claim(s) must be asserted on the form in the manner prescribed on the notice form.

(ii) When a person submits information in an attachment, the claim(s) must be asserted in the attachment as described on the notice form.

(2) The person must submit two copies of each notice form and any attachments if any information is claimed confidential.

(i) One copy of the form and attachments must be complete. In that copy, the submitter must mark the information which is claimed confidential in the manner prescribed on the notice form.

(ii) The second copy must be complete except that all information claimed as confidential in the first copy must be deleted. EPA will place the second copy in the public file.

(iii) If the submitter does not provide the second copy, the submission is incomplete and the notice review period does not begin to run until EPA receives the second copy, in accordance with § 720.65(c)(vi).

(c) EPA will disclose information that is subject to a claim of confidentiality asserted under this section only to the extent permitted by the Act, this Subpart, and Part 2 of this Title.

(d) If a notice submitter does not assert a claim of confidentiality for information at the time it is submitted to EPA, EPA may make the information public and place it in the public file without further notice to the submitter (OMB Control No. 2070–0012).

§ 720.85 Chemical identity.

(a) *Claims applicable to the period prior to commencement of manufacture or import.* (1)(i) A person who submits information to EPA under this Part may assert a claim of confidentiality for the chemical identity of the new chemical substance. This claim will apply only to the period prior to the commencement of manufacture or import for commercial purposes. A submitter may assert this claim only if the submitter believes that public disclosure prior to commencement of manufacture or import of the fact that anyone intends to manufacture or import the specific chemical substance for commercial purposes would reveal confidential business information.

(ii) If the notice includes a health and safety study concerning the new chemical substance and if the claim for confidentiality with respect to the chemical identity is denied in accordance with § 720.90(c), EPA will deny a claim asserted under this paragraph.

(2) Any person who asserts a claim of confidentiality for chemical identity under this paragraph must provide one of the following items at the time the notice is submitted:

(i) The generic name which was accepted by EPA in the prenotice consultation conducted under paragraph (a)(3) of this section.

(ii) One generic name that is only as generic as necessary to protect the confidential chemical identity of the particular chemical substance. The name should reveal the specific chemical identity to the maximum extent possible. The generic name will be subject to EPA review and approval at the time a notice of commencement is submitted.

(3)(i) Any person who intends to assert a claim of confidentiality for the chemical identity of a new chemical substance may seek a determination by EPA of an appropriate generic name for the substance before submitting a notice. For this purpose, the person should submit to EPA:

(A) The chemical identity of the substance.

(B) A proposed generic name(s) which in only as generic as necessary to protect the confidential chemical identity of the new chemical substance. The name(s) should reveal the chemical identity of the substance to the maximum extent possible.

(ii) Within 30 days, EPA will inform the submitter either that one of the proposed generic names is adequate or that none is adequate and further consultation is necessary.

(4) If a submitter claims chemical identity to be confidential under this paragraph, and if the submitter complies with paragraph (a)(2) of this section, EPA will issue for publication in the **Federal Register** notice described in § 720.70 the generic name proposed by the submitter or one agreed upon by EPA and the submitter.

(b) *Claims applicable to the period after commencement of manufacture or*

import. (1) Any claim of confidentiality under paragraph (a) of this section is applicable only until the substance is manufactured or imported for commercial purposes and becomes eligible for inclusion on the Inventory. To maintain the confidential status of the chemical identity when the substance is added to the Inventory, a submitter must reassert the confidentiality claim and substantiate the claim in the notice of commencement of manufacture required uner § 720.102. A submitter may not claim the chemical indentity confidential for the period after commencement of manufacture or import unless the submitter claimed the chemical identity confidential for the period prior to commencement of manufacture or import under paragraph (a) of this section.

(2)(i) A person who believes that public disclosure of the fact that anyone manfactures or imports the new chemical substance for commercial purposes would reveal confidential business information may assert a claim of confidentiality under this paragraph.

(ii) If the notice includes a health and safety study concerning the new chemical substance, and if the claim for confidentiality with respect to the chemical identity is denied in accordance with § 720.90(c), EPA will deny a claim asserted under this paragraph.

(3) Any person who asserts a confidentiality claim for chemical identity must:

(i) Comply with the requirements of paragraph (a)(3) of this section regarding submission of a generic name.

(ii) Agree that EPA may disclose to a person with a *bona fide* intent to manufacture or import the chemical substance the fact that the particular chemical substance is included on the confidential Inventory for purposes of notification under section 5(a)(1)(A) of the Act.

(iii) Have available for the particular chemical substance, and agree to furnish to EPA upon request:

(A) An elemental analysis.

(B) Either an X-ray diffraction pattern (for inorganic substances), a mass spectrum (for most other substances), or an infrared spectrum of the particular chemical substance, or if such data do not resolve uncertainties with respect to the identity of the chemical substance, additional or alternative spectra or other data to identify the chemical substance.

(iv) Provide a detailed written substantiation of the claim, by answering the following questions:

(A) What harmful effects to your competitive position, if any, do you think would result if EPA publishes on the Inventory the identity of the chemical substance? How could a competitor use such information given the fact that the identity of the substance otherwise would appear on the Inventory of chemical substances with no link between the substance and your company or industry? How substantial would the harmful effects of disclosure be? What is the casual relationship between the disclosure and the harmful effects?

(B) For what period of time should confidential treatment be given? Until a specific date, the occurrence of a specific event, or permanently? Why?

(C) Has the chemical substance been patented? If so, have you granted licenses to others with respect to the patent as it applies to the chemical substance? If the chemical substance has been patented and therefore disclosed through the patent, why should it be treated as confidential for purposes of the Inventory?

(D) Has the identity of the chemical substance been kept confidential to the extent that your competitors do not know it is being manufactured on imported for a commercial purpose by anyone?

(E) Is the fact that someone is manufacturing or importing this chemical substance for commercial purposes available to the public, e.g., in technical journals or other publications; in libraries; or in State, local, or Federal agency public files?

(F) What measures have you taken to prevent undesired disclosure of the fact that you are manufacturing or importing this substance for a commercial purpose?

(G) To what extent has the fact that you are manufacturing or importing this chemical substance for a commercial purpose been disclosed to others? What precautions have you taken in regard to these disclosures? Has this information been disclosed to the public or to competitors?

(H) In what form does this particular chemical substance leave the site of manufacture, e.g., as part of a product; in an effluent or emission stream? If so, what measures have you taken to guard against discovery of its identity?

(I) If the chemical substance leaves the site of manufacture in a product that is available to either the public or your competitors, can they identify the substance by analyzing the product?

(J) For what purpose do you manufacture or import the substance?

(K) Has EPA, another Federal agency, or any Federal court made any pertinent confidentiality determinations regarding this chemical substance? If so, copies of such determinations must be included in the substantiation.

(L) If the notice includes a health and safety study concerning the new chemical substance, the submitter must also answer the questions in § 720.90 (b)(2).

(4) If the submitter does not meet the requirements of this paragraph, EPA will deny the claim of confidentiality.

(5) (i) EPA will publish a generic name on the public Inventory if:

(A) The submitter asserts a claim of confidentiality in accordance with this pargraph.

(B) No claim for confidentiality of the specific chemical identity as part of a health and safety study has been denied in accordance with Part 2 of this Title or § 720.90.

(ii) Publication of a generic name on the public Inventory does not create a category for purposes of the Inventory. Any person who has a *bona fide* intent to manufacture or import a chemical substance which is described by a generic name on the public Inventory may submit an inquiry to EPA under § 720.25 (b) to determine whether the particular chemical substance is included on the confidential Inventory.

(iii) Upon receipt of a request described in § 720.25 (b), EPA may require the submitter which originally asserted confidentiality for a chemical substance to submit to EPA the information listed in paragraph (b) (3) (iii) of this section.

(iv) Failure to submit any of the information required under paragraph (b) (3) (iii) of this section within ten days of a request by EPA under this paragraph is a waiver of the original submitter's confidentiality claim. In this event, EPA may place the specific chemical identity on the public Inventory without further notice to the original submitter.

(6) If a submitter asserts a claim of confidentiality under this paragraph, EPA will examine the generic chemical name proposed by the submitter.

(i) If EPA determines that the generic name proposed by the submitter is only as generic as necessary to protect the confidential identity of the particular chemical substance, EPA will place that generic name on the public Inventory.

(ii) If EPA determines that the generic name proposed by the submitter is more generic than necessary to protect the confidential identity, EPA will propose in writing, for review by the submitter, an alternative generic name that will reveal the chemical identity of the chemical substance to the maximum extent possible.

(iii) If the generic name proposed by EPA is acceptable to the submitter, EPA will place that generic name on the public Inventory.

(iv) If the generic name proposed by EPA is not acceptable to the submitter, the submitter must explain in detail why disclosure of that generic name would reveal confidential business information and propose another generic name which is only as generic as necessary to protect the confidential identity. If EPA does not receive a response from the submitter within 30 days after the submitter receives the proposed name, EPA will place EPA's chosen generic name on the public Inventory. If the submitter does provide the information requested, EPA will review the response. If the submitter's proposed generic name is acceptable, EPA will publish that generic name on the public Inventory. If the submitter's proposed generic name is not acceptable, EPA will notify the submitter of EPA's choice of a generic name. Thirty days after this notification, EPA will place the chosen generic name on the public Inventory.

§ 720.87 Categories or proposed categories of uses of a new chemical substance.

(a) A person who submits information to EPA under this Part on the categories or proposed categories of use of a new chemical substance may assert a claim of confidentiality for this information.

(b) A submitter that asserts such a claim must:

(1) Report the categories or proposed categories of use of the chemical substance.

(2) Provide, in nonconfidential form, a description of the uses that is only as generic as necessary to protect the confidential business information. The generic use description will be included in the **Federal Register** notice described in § 720.70.

(c) The person must submit the information required by paragraph (b) of this section in the manner specified in the notice form.

§ 720.90 Data from health and safety studies.

(a) *Information other than specific chemical identity.* Except as provided in paragraph (b) of this section, EPA will deny any claim of confidentiality with respect to information included in a health and safety study, unless the information would disclose confidential business information concerning:

(1) Processes used in the manufacture or processing of a chemical substance or mixture.

(2) In the case of a mixture, the portion of the mixture comprised by any of the chemical substances in the mixture.

(3) Informaton which is not in any way related to the effects of a substance on human health or the environment, such as the name of the submitting company, cost or other financial data, product development or marketing plans, and advertising plans, for which the person submits a claim of confidentiality in accordance with § 720.80.

(b) *Specific chemical identity.* (1) *Claims applicable to period prior to commencement of manufacture.* A claim of confidentiality for the period prior to commencement of manufacture or import for the chemical identity of a chemical substance for which a health and safety study was submitted must be asserted in conjunction with a claim asserted under § 720.85(a).

(2) *Claims applicable to period after commencement of manufacture or import for commercial purposes.* To maintain the confidential status of the chemical identity of a chemical substance for which a health and safety study was submitted after commencement of manufacture or import, the claim must be reasserted and substantiated in conjunction with a claim under § 720.85(b). In addition to the questions set forth in § 720.85(b)(3)(iv) of this Part, the submitter must answer the following questions:

(i) Would disclosure of the chemical identity disclose processes used in the manufacture or processing of a chemical substance or mixture? Describe how this would occur. In responding to the question in § 720.85(b)(3)(iv)(A), explain what harmful competitive effects would occur from disclosure of this process information.

(ii) Would disclosure of the chemical identity disclose the portion of a mixture comprised by any of the substances in the mixture? Describe how this would occur. In responding to the question in § 720.85(b)(3)(iv)(A), explain what harmful competitive effects would occur from disclosure of this information.

(iii) Do you assert that disclosure of the chemical identity is not necessary to interpret any of the health and safety studies you have submitted? If so, explain how a less specific identity would be sufficient to interpret the studies.

(c) *Denial of confidentiality claim.* EPA will deny a claim of confidentiality for chemical identity under paragraph (b) of this section, unless:

(1) The information would disclose processes used in the manufacture or processing of a chemical substance or mixture.

(2) In the case of a mixture, the information would disclose the portion of the mixture comprised by any of the substances in the mixture.

(3) The specific chemical identity is not necessary to interpret a health and safety study.

(d) *Use of generic names.* When EPA discloses a health and safety study containing a specific chemical identity, which the submitter has claimed confidential, and if the Agency has not denied the claim under paragraph (c) of this section, EPA will identify the chemical substance by the generic name selected under § 720.85. (OMB Control No. 2070-0012)

§ 720.95 Public file.

All information submitted with a notice, including any health and safety study and other supporting documentation, will become part of the public file for that notice, unless such materials are claimed confidential. In addition, EPA may add materials to the public file, subject to Subpart E of this Part. Any of the nonconfidential material described above will be available for public inspection in the Office of Toxic Substances Public Reading Room, Rm. E-107, 401 M St., SW., Washington, DC 20460, during normal business hours.

Subpart F—Commencement of Manufacture or Import

§ 720.102 Notice of commencement of manufacture or import.

(a) *Applicability.* Any person who commences to manufacture or import a new chemical substance for a commercial purpose for which that person previously submitted a section 5 notice under this Part must submit a notice of commencement of manufacture or import.

(b) *When to report.* (1) If manufacture or import for commercial purposes begins on or after the effective date of this rule, the submitter must submit the notice to EPA on the first day of such manufacture or import.

(2) If manufacture or import for commercial purposes began or will begin before the effective date of this rule, the submitter must submit the notice by the effective date of this rule.

(c) *Information to be reported.* The notice must contain the following information: specific chemical identity, premanufacture notice number, and the date when manufacture or import commences. If the person claimed chemical identity confidential in the commencement notice, and wants the identity to be listed on the confidential

Inventory, the claim must be reasserted and substantiated in accordance with § 720.85(b). Otherwise, EPA will list the specific chemical identity on the public Inventory (OMB Control No. 2070–0012).

Subpart G—Compliance and Inspections

§ 720.120 Compliance.

(a) Failure to comply with any provision of this Part is a violation of section 15 of the Act (15 U.S.C 2614).

(b) A person who manufactures or imports a new chemical substance before a notice is submitted and the notice review period expires is in violation of section 15 of the Act even if that person was not requied to submit the notice under § 720.22 of this Part.

(c) Using for commercial purposes a chemical substance or mixture which a person knew or had reason to know was manufactured, processed, or distributed in commerce in violation of section 5 of this rule is a violation of section 15 of the Act (15 U.S.C. 2614).

(d) Failure or refusal to establish and maintain records or to permit access to or copying of records, as required by the Act, is a violation of section 15 of the Act (15 U.S.C. 2614).

(e) Failure or refusal to permit entry or inspection as required by section 11 is a violation of section 15 of the Act (15 U.S.C. 2614).

(f) Violators may be subject to the civil and criminal penalties in section 16 of the Act (15 U.S.C. 2615) for each violation. Persons who submit materially misleading or false information in connection with the requirements of any provision of this rule may be subject to penalties calculated as if they never filed their notices.

(g) EPA may seek to enjoin the manufacture or processing of a chemical substance in violation of this rule or act to seize any chemical substance manufactured or processed in violation of this rule or take other actions under the authority of section 7 of this Act (15 U.S.C. 2606) or section 17 or this Act (15 U.S.C. 2616).

§ 720.122 Inspections.

EPA will conduct inspections under section 11 of the Act to assure compliance with section 5 of the Act and this rule, to verify that information submitted to EPA under this rule is true and correct, and to audit data submitted to EPA under this rule.

BILLING CODE 6560-50-M

Appendix A—Premanufacture Notice for New Chemical Substances

O.M.B. No. 2070-0012: Approval Expires 3-3-86

EPA United States Environmental Protection Agency

PREMANUFACTURE NOTICE FOR NEW CHEMICAL SUBSTANCES

When completed send this form to:

DOCUMENT CONTROL OFFICER
OFFICE OF TOXIC SUBSTANCES, TS-793
U.S. E.P.A.
401 M STREET, SW
WASHINGTON, D.C. 20460

AGENCY USE ONLY

Date of receipt

Enter the total number of pages in the Premanufacture Notice →

Document control number

EPA case number

GENERAL INSTRUCTIONS

You must provide all information requested in this form to the extent that it is known to or reasonably ascertainable by you. Make reasonable estimates if you do not have actual data.

Before you complete this form, you should read the "Instructions Manual for Premanufacture Notification" (**Instructions Manual**).

Part I. GENERAL INFORMATION

You must provide the chemical identity of the new chemical substance, even if you claim the identity as confidential. You may authorize another person to submit the identity for you, but your submission will not be complete and review will not begin until EPA receives this information.

Part II. HUMAN EXPOSURE AND ENVIRONMENTAL RELEASE

You may need additional copies of part II, sections A and B if there are several manufacture, processing, or use operations that you will describe in the notice. You should reproduce these sections as needed.

Part III. LIST OF ATTACHMENTS

You should attach additional sheets if you do not have enough space on the form to answer a question fully. In part III, list these attachments, any test data or other data, and any optional information that you include in the notice.

OPTIONAL INFORMATION

You may include in the notice any information that you want EPA to consider in evaluating the new substance. The **Instructions Manual** identifies categories of optional information that you may want EPA to review.

CONFIDENTIALITY CLAIMS

You may claim any information in this notice as confidential. To assert a claim on the form, mark (X) the confidential box next to the information that you claim as confidential. To assert a claim in an attachment, circle or bracket the information you claim as confidential. If you claim information in the notice as confidential, you must provide a sanitized version of the notice, including attachments, to EPA with your submission. For additional instructions on claiming information as confidential, read the **Instructions Manual.**

Indicate below the categories of information you have claimed as confidential in the notice.

1 ☐ SUBMITTER IDENTITY
2 ☐ CHEMICAL IDENTITY
3 ☐ PRODUCTION VOLUME
4 ☐ USE INFORMATION
5 ☐ PROCESS INFORMATION
6 ☐ PORTIONS OF A MIXTURE
7 ☐ OTHER INFORMATION

TEST DATA AND OTHER DATA

You are required to submit all test data in your possession or control and to provide a description of all other data known to or reasonably ascertainable by you if these data are related to the health and environmental effects of the manufacture, processing, distribution in commerce, use, or disposal of the new chemical substance. Standard literature citations may be submitted for data in the open scientific literature. Complete test data, not summaries of data, must be submitted if they do not appear in the open literature. Following are examples of test data and other data. You should submit these data according to the requirements of §720.50 of the Premanufacture Notification Rule (40 CFR Part 720).

Test data

- **Environmental fate data**
  - Spectra (UV, visible, and infrared)
  - Density of liquids and solids
  - Water solubility
  - Melting point/melting range
  - Boiling point/boiling range
  - Vapor pressure
  - Partition coefficient, n-octanol/water
  - Biodegradation
  - Hydrolysis (as a function of pH)
  - Photochemical degradation
  - Adsorption/desorption to soil types
  - Dissociation constant
  - Other physical/chemical properties
- **Health effects data**
  - Mutagenicity
  - Carcinogenicity
  - Teratogenicity
  - Acute toxicity
  - Repeated dose toxicity
  - Metabolism studies
  - Sensitization
  - Irritation
- **Environmental effects data**
  - Microbial and algal toxicity
  - Terrestrial vascular plant toxicity (e.g., seed germination studies, growth inhibition)
  - Acute and chronic toxicity to animals (e.g., fish, birds, mammals, invertebrates)

Other data

- **Risk assessments**
- **Structure/activity relationships**
- **Test data not in the possession or control of the submitter**

CERTIFICATION

I certify that to the best of my knowledge and belief:

1. The company named in part I, section A, subsection 1a of this notice form intends to manufacture or import for a commercial purpose, other than in small quantities solely for research and development, the substance identified in part I, section B.

2. All information provided in this notice is complete and truthful as of the date of submission.

3. I am submitting with this notice all test data in my possession or control and a description of all other data known to or reasonably ascertainable by me as required by §720.50 of the Premanufacture Notification Rule.

		Confidential
Signature of authorized official	Date	
Signature of agent — *(if applicable)*	Date	

Part I — GENERAL INFORMATION

Section A — SUBMITTER IDENTIFICATION

Mark (X) the "Confidential" box next to any subsection you claim as confidential.

				Confidential
1a. Person submitting notice	Name of authorized official		Title	
	Company			
	Mailing address (number and street)			
	City, State, ZIP code			
b. Agent *(if applicable)*	Name of authorized official		Title	
	Company			
	Mailing address (number and street)			
	City, State, ZIP code			
c. *If you are submitting this notice as part of a joint submission, mark (X) this box.* → ☐				
2. Technical contact	Name		Title	
	Company			
	Mailing address (number and street)			
	City, State, ZIP code	Telephone: Area code	Number	
3. If you have had a prenotice communication (PC) concerning this notice and EPA assigned a PC Number to the notice, enter the number →			*Mark (X) if none* → ☐	
4. If you have submitted a test-marketing exemption (TME) application for the chemical substance covered by this notice, enter the TME number assigned by EPA →			*Mark (X) if none* → ☐	
5. If you have submitted a bona fide request for the chemical substance covered by this notice, enter the bona fide request number assigned by EPA →			*Mark (X) if none* → ☐	

6. Type of Notice — *Mark (X)* 1 ☐ Manufacture 2 ☐ Import

Part I — GENERAL INFORMATION — Continued

Section B — CHEMICAL IDENTITY INFORMATION

Mark (X) the "Confidential" box next to any item you claim as confidential.

Complete either item 1 or 2 as appropriate. Complete all other items.

If another person will submit chemical identity information for you, mark (X) the box at the right. → ☐
Identify the name, company, and address of that person in a continuation sheet.

Confidential

1. **Class 1 or 2 chemical substances** (for definitions of class 1 and class 2 substances, see the **Instructions Manual**)

a. Class of substance — *Mark (X)* 1 ☐ Class 1 2 ☐ Class 2

b. Chemical name (preferably CAS or IUPAC nomenclature)

c. Molecular formula and CAS Registry Number (if known)

d. For a class 1 substance, provide a structural diagram. For a class 2 substance — (1) List the immediate precursor substances with their respective CAS Registry Numbers. (2) Describe the nature of the reaction or process. (3) Indicate the range of composition and the typical composition (where appropriate). (4) Provide a representative structural diagram (if possible).

☐ *Mark (X) this box if you attach a continuation sheet.*

Part I — GENERAL INFORMATION — Continued

Section B — CHEMICAL IDENTITY INFORMATION — Continued

2. Polymers (For a definition of polymer, see the **Instructions Manual**.)

Confidential

a. Indicate the **lowest** number-average molecular weight composition of the polymer you intend to manufacture. Indicate the **maximum** weight percent of low molecular weight species below 500 and below 1,000 absolute molecular weight of that composition. Describe the methods of measurement or the bases for your estimates.

☐ *Mark (X) this box if you attach a continuation sheet.*

b. You must make separate confidentiality claims for monomer or other reactant identity, composition information, and residual information. Mark (X) the "Confidential" box next to any item you claim as confidential.

(1) — Provide the chemical name and CAS Registry Number of each monomer or other reactant used in the manufacture of the polymer.
(2) — Indicate the **typical** weight percent of each monomer or other reactant in the polymer.
(3) — Mark (X) the identity column if you want a monomer or other reactant used at two weight percent or less to be listed as part of the polymer description on the TSCA Chemical Substance Inventory.
(4) — Indicate the **maximum** weight percent of each monomer or other reactant that may be present as a residual in the polymer as manufactured for commercial purposes.

Monomer or other reactant and CAS Registry Number (1)	Confidential	Typical composition (2)	Identity *Mark (X)* (3)	Confidential	Maximum residual (4)	Confidential
		%			%	
		%			%	
		%			%	
		%			%	
		%			%	
		%			%	
		%			%	

☐ *Mark (X) this box if you attach a continuation sheet.*

c. Provide a representative structural diagram of the polymer, if possible.

☐ *Mark (X) this box if you attach a continuation sheet.*

Part I — GENERAL INFORMATION — Continued

Section B — CHEMICAL IDENTITY INFORMATION — Continued

3. Impurities

(a) — Identify each impurity that may be reasonably anticipated to be present in the chemical substance as manufactured for commercial purposes. Provide the CAS Registry Number if available. If there are unidentified impurities, enter "unidentified."

(b) — Estimate the **maximum** weight percent of each impurity. If there are unidentified impurities, estimate their total weight percent.

Impurity and CAS Registry Number (a)	Maximum percent (b)	Confidential
	%	
	%	
	%	
	%	
	%	
	%	
	%	

☐ *Mark (X) this box if you attach a continuation sheet.*

4. Synonyms — Enter any synonyms for the new chemical substance identified in subsection 1 or 2. (Confidential)

☐ *Mark (X) this box if you attach a continuation sheet.*

5. Trade identification — List trade names for the new chemical substance identified in subsection 1 or 2.

☐ *Mark (X) this box if you attach a continuation sheet.*

6. Generic chemical name — If you claim chemical identity as confidential, enter the generic chemical name that you developed with EPA during prenotice communication. If you have not developed a generic name with EPA, provide a generic name that reveals the specific chemical identity of the new chemical substance to the maximum extent possible. Read the TSCA Chemical Substance Inventory, Initial Inventory, Volume I for guidance on developing generic names.

☐ *Mark (X) this box if you attach a continuation sheet.*

7. Byproducts — Describe any byproducts resulting from the manufacture, processing, use, or disposal of the new chemical substance at sites you control. Provide the CAS Registry Number if available.

Byproduct (1)	CAS Registry Number (2)	Confidential

☐ *Mark (X) this box if you attach a continuation sheet.*

Part I — GENERAL INFORMATION — Continued

Section C — PRODUCTION, IMPORT, AND USE INFORMATION

Mark (X) the "Confidential" box next to any item you claim as confidential.

1. Production volume — Estimate the **maximum** production volume during the first 12 months of production. Also estimate the ***maximum*** *production volume for any consecutive 12-month period during the first three years of production.*

Maximum first 12-month production (kg/yr)	Maximum 12-month production (kg/yr)	Confi-denti

2. Use Information

You must make separate confidentiality claims for the description of the category of use, the percent of production volume devoted to each category, the formulation of the new substance, and other use information. Mark (X) the "Confidential" box next to any item you claim as confidential.

a. (1) — Describe each intended category of use of the new chemical substance by function and application.
(2) — Estimate the percent of total production for the first three years devoted to each category of use.
(3) — Estimate the percent of the new substance as formulated in mixtures, suspensions, emulsions, solutions, or gels as manufactured for commercial purposes at sites under your control associated with each category of use.
(4) — Mark (X) whether the use is site-limited, industrial, commercial, or consumer. Mark more than one column if appropriate.
Read the **Instructions Manual** for examples.

Category of use (1)	Confi-dential	Production (percent) (2)	Confi-dential	Formulation (percent) (3)	Confi-dential	*Mark (X) appropriate column(s)* (4) Site-limited	Industrial	Commercial	Consumer	Confi-denti
		%		%						
		%		%						
		%		%						
		%		%						

☐ *Mark (X) this box if you attach a continuation sheet.*

b. Generic use description — If you claim any category of use description in subsection 2a as confidential, enter a generic description of that category. Read the **Instructions Manual** for examples of generic use descriptions.

☐ *Mark (X) this box if you attach a continuation sheet.*

3. Hazard Information — Include in the notice a copy or reasonable facsimile of any hazard warning statement, label, material safety data sheet, or other information which will be provided to any person regarding protective equipment or practices for the safe handling, transport, use, or disposal of the new chemical substance. List in part III any hazard information you include.

☐ *Mark (X) this box if you attach hazard information.*

Part II — HUMAN EXPOSURE AND ENVIRONMENTAL RELEASE

Section A — INDUSTRIAL SITES CONTROLLED BY THE SUBMITTER

Complete section A for each type of manufacture, processing, or use operation involving the new chemical substance at industrial sites you control.

Mark (X) the "Confidential" box next to any item you claim as confidential.

1. Operation description

a. Identity— Enter the identity of the site at which the operation will occur. — **Confidential**

Name

Site address (number and street)

City, County, State, ZIP code

If the same operation will occur at more than one site, enter the number of sites. → Identify the additional sites on a continuation sheet.

☐ *Mark (X) this box if you attach a continuation sheet.*

b. Type — *Mark (X)*

1 ☐ Manufacturing 2 ☐ Processing 3 ☐ Use

c. Amount and Duration — *Complete 1 or 2 as appropriate*

1. Batch	Maximum kg/batch	Hours/batch	Batches/year
2. Continuous	Maximum kg/day	Hours/day	Days/year

d. Process description

(1) Diagram the major unit operation steps and chemical conversions.

(2) Provide the identity, the approximate weight (by kg/day or kg/batch), and entry point of all feedstocks (including reactants, solvents, and catalysts).

(3) Identify by number the points of release to the environment of the new chemical substance.

☐ *Mark (X) this box if you attach a continuation sheet.*

Part II — HUMAN EXPOSURE AND ENVIRONMENTAL RELEASE — Continued

Section A — INDUSTRIAL SITES CONTROLLED BY THE SUBMITTER — Continued

2. Occupational Exposure

You must make separate confidentiality claims for the description of worker activity, physical form of the new chemical substance, number of workers exposed, and duration of activity. Mark (X) the "Confidential" box next to any item you claim as confidential.

(1) — Describe the activities in which workers may be exposed to the new chemical substance. Include activities in which workers wear protective equipm
(2) — Indicate the physical form(s) of the new chemical substance at the time of exposure.
(3) — Estimate the maximum number of workers involved in each activity.
(4) and (5) — Estimate the maximum duration of the activity for any worker in hours per day and days per year.

Worker activity (1)	Confidential	Physical form(s) (2)	Confidential	Maximum number (3)	Confidential	Maximum duration		C de
						Hrs/day (4)	Days/yr (5)	

☐ *Mark (X) this box if you attach a continuation sheet.*

3. Environmental Release and Disposal

You must make separate confidentiality claims for the release number and the amount of the new chemical substance released and other release and disposal information. Mark (X) the "Confidential" box next to each item you claim as confidential.

(1) — Enter the number of each release point identified in the process description, part II, section A, subsection 1d(3).
(2) — Estimate the amount of the new chemical substance released directly to the environment or into control technology (in kg/day or kg/batch).
(3) — Identify the media (air, land, or water) to which the new substance will be released from that release point.
(4) — Describe control technology, if any, that will be used to limit the release of the new substance to the environment. For releases disposed of on land, characterize the disposal method.
(5) — Identify the destination(s) of releases to water.

Release Number (1)	Amount of new substance released (2)	Confidential	Media of release (3)	Control technology (4)	Con dent

(5) Mark (X) the destination(s) of releases to water. 1 ☐ POTW (publicly owned treatment works) 3 ☐ Other — *Specify*
2 ☐ Navigable waterway

☐ *Mark (X) this box if you attach a continuation sheet.*

Part II — HUMAN EXPOSURE AND ENVIRONMENTAL RELEASE — Continued

Section B — INDUSTRIAL SITES CONTROLLED BY OTHERS

Complete section B for each type of processing or use operation involving the new chemical substance at sites you do not control.

*To claim information in this section as confidential, circle or bracket the **specific** information that you claim as confidential.*

Operation description

Describe the typical processing or use operation. Identify the unit operation steps which may occur during the operation. Estimate the number of sites at which the operation is likely to occur. Identify situations in which worker exposure to and/or environmental release of the new chemical substance may occur. Estimate the percent of new chemical substance as formulated in products manufactured for commercial purposes in the operation or as used in the operation. Estimate the number of workers exposed and the duration of exposure. Identify controls which limit worker exposure and environmental release if typically used. Identify byproducts which may result from the operation.

☐ *Mark (X) this box if you attach a continuation sheet.*

Part III — LIST OF ATTACHMENTS

Attach continuation sheets for sections of the form and test data and other data (including physical/chemical properties and structure/activity information), and optional information after this page. Clearly identify the attachment and the section of the form to which it relates, if appropriate. Number consecutively the pages of the attachments. In the column below, enter the inclusive page numbers of each attachment.

Mark (X) the "Confidential" box next to any attachment **name** you claim as confidential. Read the ***Instructions Manual*** for guidance on how to claim any information in an attachment as confidential. You must include with the sanitized copy of the notice form a sanitized version of any attachment in which you claim information as confidential.

Attachment name	Attachment page number(s)	**Confi-dential**

☐ *Mark (X) this box if you attach a continuation sheet. Enter the attachment name and number.*

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